



**Universidade de Coimbra
Faculdade de Medicina**

***PROCEDIMENTOS NORMALIZADOS PARA
PESQUISA DE INFORMAÇÃO CLÍNICA
SOBRE REACÇÕES ADVERSAS NO ÂMBITO
DA INFECÇÃO VIH / SIDA***

Catarina Isabel Pereira Laginhas Loureiro Abrantes

Coimbra - 2009



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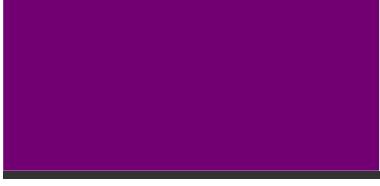
Coimbra - 2009

**Dissertação de Mestrado em Síndroma de Imunodeficiência Adquirida (SIDA): da
Prevenção à Terapêutica, área de especialização em Educação para a Saúde e
Medicina**

apresentada à Faculdade de Medicina da Universidade de Coimbra

realizada sob a orientação da Professora Doutora Isabel Vitória Figueiredo e do
Professor Doutor António Meliço-Silvestre

*A “Vó Pitita”, ao Avô Acrísio e à Tia Maria,
para sempre na memória e no coração*



AGRADECIMENTOS

Sem lugar posto, o eu sabedor
Sofreado pelo deglutiir da ansiedade
Entrei pela porta mestra, sem leviandade
E parti... pelo caminho doutor!

Nos primeiros passos, um sorriso cravado
Seguidos de uma angústia lachtejada
Que, vergada perante um coração aliviado
Pela vitória atingida, vejo o meu MUITO OBRIGADA...

... à Professora Doutora Isabel Vitória Figueiredo, a mão empolgante que logo se estendeu e me empurrou em frente,

... ao Professor Doutor António Meliço-Silvestre, o “sim” emocionalmente ouvido na colaboração prestada e a esperança nas descobertas vindouras no conhecimento da infecção VIH / SIDA,

... à Professora Doutora Ana Cristina Rama, a consciência de toda esta científica aventura,

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... à Professora Doutora Maria Margarida Caramona, o meu louvor eterno pela paixão por esta vida farmacêutica,

... aos meus colegas de Mestrado, a partilha de experiências de vida em tudo diferentes,

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... a todos, sem excepção e sem mais palavras, que me conduziram a mais esta etapa final do curso da minha vida!



ABREVIATURAS E SIGLAS

ABREVIATURAS

ed(s).	edição(ões)
et al.	e outros
etc.	entre outras coisas
h	hora
kg	quilograma
L	litro
p.	página

SIGLAS

ADN	Ácido desoxirribonucleico
ARN	Ácido ribonucleico
ATC	Classificação Anatómica Terapêutica Química adoptada pela Organização Mundial de Saúde
ATP	Adenosina trifosfato
CYP	Citocromo P 450
CCR5	Receptor de quimiocinas do tipo 5 com o domínio CC
CD4, CD8	Grupo de diferenciação de linfócitos
CXCR4	Receptor de quimiocinas do tipo 4 com o domínio CXC
DRESS	Síndroma caracterizado por uma erupção farmacológica com eosinofilia e sintomas sistémicos
ELISA	Teste imunoenzimático
HAART	Terapêutica anti-retrovírica de alta eficácia
HDL	Lipoproteínas de alta densidade
HLA	Antigénio leucocitário humano
LDL	Lipoproteínas de baixa densidade
MIP	Proteína inflamatória de macrófagos
PCR	Reacção em cadeia pela polimerase
RANTES	Quimiocina regulada sob activação normalmente expressada e secretada por células T
SIDA	Síndroma de Imunodeficiência Adquirida
SIMcpz	Vírus da Imunodeficiência dos Símios do chimpanzé
SIMsm	Vírus da Imunodeficiência dos Símios do macaco
VIH	Vírus da Imunodeficiência Humana
VLDL	Lipoproteínas de muito baixa densidade



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RESUMO

ABSTRACT

A terapêutica anti-retrovírica constitui a verdadeira revolução na epidemiologia da infecção VIH / SIDA. A adopção de regimes terapêuticos combinados permite um controlo mais rigoroso da evolução da doença e um aumento da qualidade de vida do doente, embora as reacções adversas associadas possam condicionar a adesão à terapêutica, o desenvolvimento de resistências e a perda de futuras opções de tratamento.

A procura de informação relativa a resultados clínicos negativos da terapêutica anti-retrovírica na literatura científica, com base no conceito de Medicina Baseada na Evidência, motivou o desenvolvimento deste trabalho em duas partes, na base de dados bibliográfica de acesso gratuito MEDLINE, através do operador PubMed.

O objectivo geral proposto consiste na optimização de uma metodologia sistematizada de pesquisa de Informação Clínica, avaliada com base na relação entre os parâmetros sensibilidade e especificidade e tendo como referência uma estratégia de pesquisa genérica desenvolvida para a busca de informação relativa a iatrogenia medicamentosa.

Na primeira parte do trabalho, construímos equações de pesquisa que incluíram termos MeSH referentes à classe farmacológica, “*subheadings*” relativos a reacções adversas e o filtro qualitativo relativo ao tipo de estudo, para identificação e análise da prevalência dos resultados negativos da terapêutica anti-retrovírica descritos em casos clínicos. Os resultados obtidos coincidiram com as reacções adversas características dos fármacos anti-retrovíricos, apesar do número de artigos recuperado ser pouco significativo.

Na segunda parte do trabalho, procedemos à construção de equações de pesquisa em três fases, num nível crescente de complexidade, com a introdução e combinação de termos MeSH correspondentes às classes de fármacos anti-retrovíricos, “*subheadings*” relativos a reacções adversas, filtros qualitativos relativos ao tipo de estudo (estudo de casos, revisões sistemáticas e ensaios clínicos aleatorizados), palavras-chave relativas à situação clínica indexadas em MeSH e “*subheadings*” relativos à situação clínica, com vista à optimização da metodologia de pesquisa.

A respectiva apreciação, baseada nos valores da sensibilidade e especificidade calculados, mostra a importância do filtro qualitativo relativo ao tipo de estudo, uma vez que a informação relativa a resultados clínicos negativos da terapêutica anti-retrovírica é encontrada, fundamentalmente, em casos clínicos referenciados na literatura.

A originalidade do trabalho nesta área comprova e reforça a real necessidade de uma gestão do risco dos resultados clínicos negativos da terapêutica, para obtenção de melhores resultados, e a importância crescente do conhecimento e aprendizagem da procura da evidência em fontes credíveis que, conjugada com o sentido crítico individual e com as características do doente, serve de suporte à decisão clínica.

Development of antiretroviral therapy is the true turning-point in the treatment of HIV infection, allowing a best rigorous control of infection's progress and a better quality of patient's life. Related adverse drug effects can determine non-compliance, leading to resistance development and loss of future treatment options.

Finding published adverse drug effects of antiretroviral agents, using an evidence-based approach, and optimizing a systematic methodology of that kind of clinical information search in MEDLINE, through PubMed, assessed by the parameters sensibility and specificity, is the main purpose of this work divided in two sections. A generic search strategy developed to find information related to drug iatrogenic was considered as a reference to the development of search studied strategies.

In first section, we combined MeSH terms related to the different antiretroviral agents, subheadings linked to adverse effects and a qualitative filter related to study design. With that search strategies, we identified and analyzed the prevalence of adverse effects of antiretroviral agents described in case reports. The results presented are similar to characteristic adverse effects of antiretroviral agents, despite the fact that the number of articles retrieved was less significant.

The second section was divided in three phases with a growing complexity level. We introduced and combined MeSH terms related to the different antiretroviral agents, *subheadings* linked to adverse effects and a qualitative filter related to study design (case reports, systematic reviews and randomized controlled trials), indexed MeSH keywords related to the clinical situation and *subheadings* related to the clinical situation, to create different search strategies to optimize the proposed methodology.

Their assessment by means of sensibility and specificity shows the importance of the qualitative filter used, because adverse effects of antiretroviral agents are mainly found in case reports.

As the first work that approaches two different concepts simultaneously, adverse effects of antiretroviral agents and an evidence based medicine approach to search literature, it demonstrates and reinforces the real need for information, as way for risk management of adverse effects, to obtain better results, and the importance of knowing and learning evidence based practice in credible sources to support clinical decisions, integrated with clinical expertise and patient's values.



INTRODUÇÃO

Introdução

“Saúde é um completo estado de bem-estar físico, mental e social e não apenas a ausência de doenças.”

Organização Mundial de Saúde, 1948

Introdução

Desde os primórdios da Antiguidade que o estado saúde / doença suscita particular interesse na sua interpretação causal em que determinados agentes e/ou hospedeiros e o meio ambiente se relacionam, definindo ou a homeostase ou o desequilíbrio corporais.(1)

1981... Eis o desabrochar da pandemia com a detecção, em grupos de homossexuais dos Estados Unidos da América, de sintomas associados a tipos raros de doenças – pneumonia por *Pneumocystis jiroveci* e sarcoma de Kaposi, tornados fiéis diagnósticos definidores, entre outros, daquela que viria a ser designada de Síndroma de Imunodeficiência Adquirida cujo agente causador, isolado separadamente pelas equipas de Gallo e Montagnier, coincidiria com o Vírus da Imunodeficiência Humana.(2-8)

As proporções atingidas são de tal forma catastróficas que, segundo os últimos dados epidemiológicos disponíveis(9,10), 33 milhões de pessoas encontram-se infectadas em todo o Mundo, tendo-se também registado até 2007, 25 milhões de mortes por SIDA. A região da África Sub-Sahariana destaca-se com 67% das pessoas infectadas, continuando o Síndroma de Imunodeficiência Adquirida a ocupar o lugar de principal causa de morte nestes países.

De qualquer modo, os esforços desenvolvidos têm-se reflectido na diminuição do aparecimento de novas infecções e do número de mortes relacionadas com a SIDA (2,7 milhões de diagnósticos e 2 milhões de mortes em 2007), embora ainda não se detenha o domínio do controlo da infecção em nenhuma parte do Mundo.

Em Portugal, até 31 de Dezembro de 2008, o Núcleo de Vigilância Laboratorial de Doenças Infecciosas da Unidade de Referência e Vigilância Epidemiológica do Departamento de Doenças Infecciosas do Instituto Nacional de Saúde Doutor Ricardo Jorge em cooperação com a Coordenação Nacional para a infecção VIH / SIDA(11), registou 34888 casos notificados de infecção nos seus diferentes estádios, sendo 15020 casos de SIDA, distribuídos não equitativamente pelas regiões do país.

Nesse sentido, debruçando-nos sobre a ciência farmacológica, um dos primeiros conceitos que nos reaviva a memória reside na dualidade fármaco *versus* veneno(12), ou seja, o efeito curativo exercido, por uma determinada substância de origem natural ou sintética, sobre aquele(s) órgão(s) ou tecido(s), suplementado, muitas vezes, simultânea ou mais tarde e consoante a dose administrada e as características individuais de cada um, pelo desencadear de outras reacções, potencialmente adversas influenciáveis da rotina do quotidiano.(13)

A terapêutica anti-retrovírica, propulsora, desde a sua descoberta, da ascensão de uma auto-estima e de uma esperança à beira do precipício de todos os que viviam diariamente o drama da infecção VIH / SIDA, não foge à regra, acarretando consigo estes “fardos” adversos, desvantajosos e, nalguns casos, particularmente inestéticos, que impossibilitam o doente infectado de aderir convenientemente à terapêutica, retrocedendo e regressando ao caminho da solidão e do preconceito evitáveis.

Introdução

A bibliografia publicada nesta área evidencia a preocupação e o estímulo de urgência de quem, com responsabilidades profissionais, mas, acima de tudo, como um novo membro integrado forçosamente no seio daquela família devastada, quer, a todo o custo, aliviar, desaparecer, esclarecer as dúvidas, os porquês doridos e infundáveis com vista ao alcançar do propósito das suas funções – o recuperar da saúde, qualidade de vida e dignidade do ser humano.

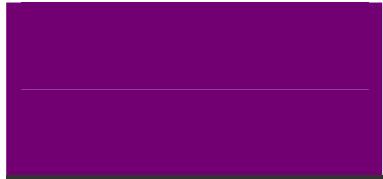
A necessidade de aquisição de competências nos campos da tecnologia e do conhecimento repercutem-se na qualidade de informação na área da saúde crescente em objectividade, rapidez, fiabilidade, acuidade, e demonstrada na decisão clínica a tomar pelo profissional de saúde para aquele doente que apresenta determinados sinais e sintomas definidores de um determinado diagnóstico requerente de uma terapêutica específica.

Assim, o enquadramento teórico deste trabalho inicia-se com a Infecção VIH / SIDA no qual relembramos sumariamente os aspectos importantes relacionados com o Vírus da Imunodeficiência Humana cuja acção infecciosa evoluirá naturalmente para o Síndrome de Imunodeficiência Adquirida, sendo combatida com a revolucionária terapêutica anti-retrovírica, extremamente eficaz, embora com inconvenientes reacções adversas, principal objecto de estudo do trabalho, passíveis de condicionar a adesão à terapêutica, o desenvolvimento de resistências e a perda de futuras opções de tratamento.

Segue-se a apresentação dos conceitos e etapas implícitos a todo o processo inerente à Medicina Baseada na Evidência, impulsionadora de uma busca de informação bibliográfica rápida e válida, tendo em conta as características e valores de determinado doente.

A investigação desenrola-se com a descrição das reacções adversas relatadas na base de dados MEDLINE, através do operador PubMed, e com a aplicação e optimização de um método baseado nos conceitos referidos em epígrafe, recorrendo, na sua validação, à apreciação do grau de relação entre dois instrumentos de medida utilizados para o efeito.

Os resultados obtidos, a respectiva discussão e as conclusões pretendem demonstrar a mais valia deste trabalho na satisfação das necessidades de informação de qualquer interveniente no Sistema de Saúde e, consequentemente, visar a melhoria da prática clínica diária traduzida, sempre, na qualidade de vida do doente.



OBJECTIVOS

Objectivos

O objectivo do trabalho em curso consiste na optimização de uma metodologia sistematizada de pesquisa de Informação Clínica, na MEDLINE, relativa a iatrogenia medicamentosa, concretamente, os resultados negativos da terapêutica anti-retrovírica, no âmbito da Medicina Baseada na Evidência, avaliada com base na relação entre os parâmetros sensibilidade e especificidade.

Em concreto, pretendemos:

- Identificar e analisar a prevalência dos resultados clínicos negativos da terapêutica anti-retrovírica descritos em casos clínicos na literatura científica.
- Optimizar a metodologia de pesquisa bibliográfica, na MEDLINE, dos resultados clínicos negativos da terapêutica anti-retrovírica, com a introdução e combinação consecutivas de determinados elementos em diferentes equações de pesquisa, tendo como referência uma estratégia de pesquisa genérica desenvolvida para a busca de informação relativa a iatrogenia medicamentosa.
- Apreciar a referida metodologia de pesquisa com base na relação entre os parâmetros sensibilidade e especificidade, avaliadora dos resultados recuperados com as estratégias de pesquisa criadas.

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Fundamentação teórica

CAPÍTULO I



***VÍRUS DA
IMUNODEFICIÊNCIA
HUMANA***

Pertencente à família *Retroviridae* e, dentro desta, ao género *Lentivinidae*, as origens do Vírus da Imunodeficiência Humana remontam a ligações zoonóticas com primatas africanos não humanos, nomeadamente chimpanzés e macacos das espécies *Pan troglodytes troglodytes* e *Cercocebus atys*, respectivamente. Relatos dos inícios do século passado já referem que as ditas espécies eram portadoras de retrovírus estrutural e geneticamente semelhantes ao Vírus da Imunodeficiência Humana, daí a sua designação de Vírus da Imunodeficiência dos Símios do chimpanzé (SIMcpz) e do macaco (SIMsm), embora parecessem não provocar doença nos seus hospedeiros naturais. A transmissão para a espécie humana poderá ter começado por ocorrer aquando da prática de caça através do contacto com o sangue e secreções do animal ferido e do próprio manuseamento da carne para fins alimentícios.(14)

Entre outras diferenças, a análise do genoma permite a distinção do Vírus da Imunodeficiência Humana em dois tipos:

- Vírus da Imunodeficiência Humana tipo 2 (VIH-2)

Mais parecido com o SIMsm, o VIH-2 apresenta características de menor virulência(15-17), encontrando-se praticamente confinado à sua zona endémica da costa oeste africana.

- Vírus da Imunodeficiência Humana tipo 1 (VIH-1)

Mais similar com o SIMcpz, distinguem-se várias estirpes de VIH-1 que se encontram agrupadas nos grupos M (“main”), porque engloba a maioria das estirpes responsáveis pela globalização da epidemia, grupo O (“outlier”) e grupo N (“non-M / non-O”). No grupo M, a genómica ainda diferencia dez subtipos genéticos e novas linhagens recombinantes, as Formas Recombinantes Circulantes, algumas das quais ocupando um significativo domínio epidemiológico.(14,18-21)

A partícula vírica, esférica, de dimensões microscópicas, é formada por um envelope membranar de natureza lipídica que rodeia um núcleo central – nucleocapsídeo – onde se encontram as duas moléculas idênticas de ARN, o genoma característico de um retrovírus, que englobam determinados genes codificadores de importantes poliproteínas:

- *Gag* que se cliva nas proteínas constituintes do nucleocapsídeo p24, p7, p6 e p17;
- *Pol* que origina a transcriptase reversa, a integrase e a protease víricas, enzimas activas na replicação do vírus;
- *Env* que origina, primeiramente, a gp160 a qual se divide nas glicoproteínas do envelope membranar, a subunidade gp41, transmembranar, e a subunidade gp120, imprescindíveis na ligação à célula alvo.

Salientam-se, ainda, as proteínas *tat*, *rev*, *nef*, *vif*, *vpr* e *vpu*, proteínas não estruturais presentes no interior da partícula vírica que estão implicadas na replicação do vírus e no estabelecimento da infecção na célula alvo.

O alvo da acção do VIH-1, uma destruição lenta e progressiva, recai sobre o sistema imunitário, preferencialmente os linfócitos T CD4⁺, células imediatamente activas no controlo da resposta imunitária e presentes em grande quantidade nos nódulos linfáticos e órgãos linfóides, afectando em menor extensão os macrófagos e as células dendríticas.

Para isso, todo o material genético do vírus tem de ser transferido para o interior da célula alvo, objectivo crucial do processo de replicação do vírus o qual se inicia com uma interacção específica entre a glicoproteína externa do envelope vírico e receptores CD4 situados na superfície das células imunitárias referidas. Dessa interacção indutora da fixação do VIH à membrana de célula alvo, resultam alterações conformacionais na gp120 que a ligam a segundos receptores – os correceptores, que funcionam como receptores das quimiocinas, desempenhando o CCR5 (receptor β das quimiocinas) e o CXCR4 (receptor α das quimiocinas) um papel importante na transmissão e patogénese desta infecção.

Seguem-se o rompimento das ligações gp120 – gp41 e alterações conformacionais nesta glicoproteína transmembranar, com exposição da sua região peptídica, que conduzem à fusão do invólucro vírico com a membrana da célula alvo e consequente libertação do conteúdo vírico para o interior do hospedeiro.

O complexo formado entre o ARN vírico e proteínas víricas onde se inclui a transcriptase reversa é libertado do nucleocapsídeo para o citoplasma da célula alvo, começando a decorrer, à custa da referida enzima, o processo de transformação das duas moléculas de ARN numa cadeia dupla de ADN, surgindo um novo complexo que engloba o ADN recém-formado, a transcriptase reversa, a integrase e outras proteínas víricas.

Atravessado o citoplasma, o novo complexo chega ao núcleo da célula alvo onde a integrase insere o ADN recém-formado em locais específicos do genoma da célula alvo, originando o provírus.

Entretanto, o provírus pode manter-se num estado de latência ou prosseguir a sua transformação em novas partículas víricas, sofrendo um processo de transcrição com produção de grande quantidade de ARN mensageiro que é libertado para o citoplasma celular. À transcrição segue-se a tradução da informação genética do ARN em glicoproteínas e poliproteínas que, por acção da protease, se desintegram em novas proteínas víricas. Estas reúnem-se com o ARN, originando as mais recentes partículas víricas, cerca de 10^{10} a 10^{11} , diariamente, as quais sofrem uma última maturação aquando da passagem para a corrente sanguínea com a aquisição do invólucro exterior, tornando-se habilitadas para o desempenho da sua função infecciosa.(6,15,17,22-31)

A figura 1 representa esquematicamente o ciclo de vida do VIH-1.

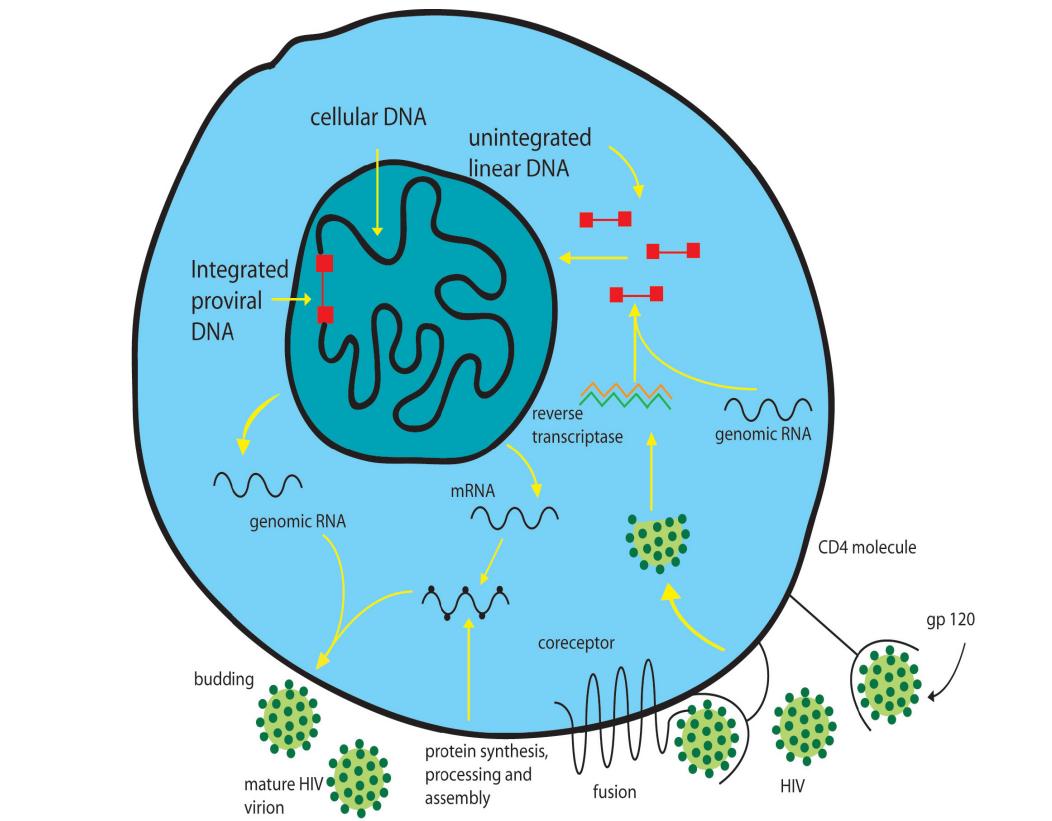


Figura 1. Esquema do ciclo de vida do VIH-1 (Wainberg et al., 2008).(31)

O início do percurso do VIH-1 no corpo humano envolve a sua transmissão por três vias possíveis:

- via sexual;
- via parentérica;
- via perinatal.

A realidade epidemiológica portuguesa reflecte as evidências ao nível dos países desenvolvidos, do aumento do número de casos por transmissão heterossexual, principalmente nas camadas jovens em idades compreendidas entre os 25 e 44 anos, mas também na população com idade superior a 50 anos, em detrimento da diminuição do número de casos ligados à administração de drogas injectáveis e da estabilização do número de infecções em indivíduos homossexuais.(11,32-34)

Factores como, a elevada carga vírica, a presença de doenças sexualmente transmissíveis ulcerativas ou exsudativas, a existência de lesões na pele ou mucosas e o consequente tempo de contacto entre os fluidos infectados e a lesão, a detecção de

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sangue durante a relação sexual, a ausência de circuncisão no homem, o número de parceiros e contactos sexuais e a probabilidade de infecção do parceiro, a prática de sexo sem protecção, a toxicodependência e outras dependências, a prostituição e a indústria do sexo, contribuem para o aumento do risco de infecção no receptor com particular enfoque para a vulnerabilidade biológica, psicossocial e comportamental da mulher.

A selecção e o estudo do sangue dos dadores com técnicas de purificação rigorosas fazem com que o número de casos de infecções por transfusões sanguíneas seja, neste momento, praticamente irrisório tal como o número de casos em hemofílicos devido à eliminação virtual do risco, com o recurso a inactivadores do vírus como o calor e o uso de certos detergentes.

A contribuição da terapêutica anti-retrovírica, a programação do parto por cesariana electiva e a proibição do aleitamento materno, constituíram um grande avanço na prevenção da transmissão perinatal em contraste com a calamidade a que se continua a assistir na África Sub-Sahariana.(6,30,35-39)



***SÍNDROMA DE
IMUNODEFICIÊNCIA
ADQUIRIDA***

O desequilíbrio entre as respostas imunológica e virológica, traduzidas nos respectivos marcadores – linfócitos T CD4⁺ e carga vírica, constitui a base da compreensão da patogénese desta infecção que, naturalmente, progride com a incapacidade de controlar a replicação vírica e a destruição da resposta imunitária desencadeada, evitando o aparecimento de doenças oportunistas e outras manifestações clínicas características do Síndrome de Imunodeficiência Adquirida, como se comprova esquematicamente com a figura 2.

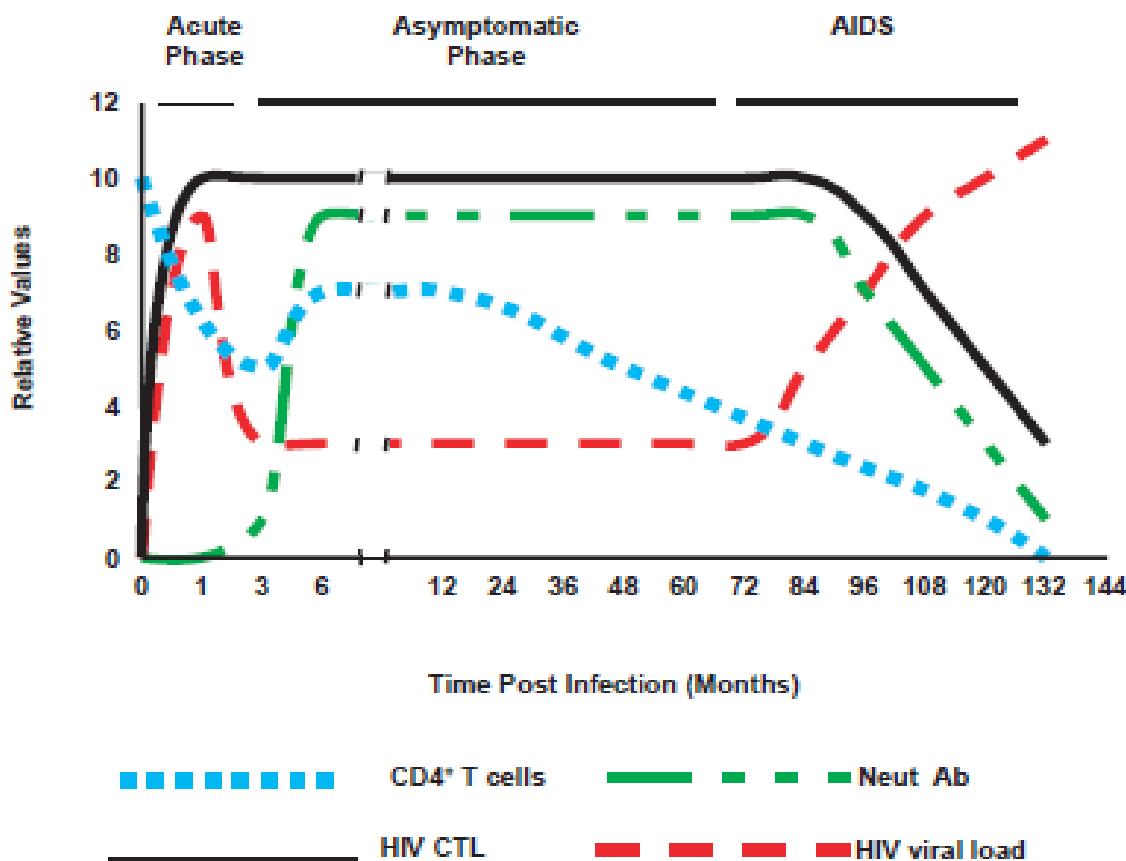


Figura 2. Evolução natural da infecção pelo VIH-1.(40)

Após a transmissão vírica, no período correspondente às duas a três semanas seguintes, surge o síndrome retrovírico agudo, o qual se manifesta, habitualmente, como um síndrome mononucleósico com febre, odinofagia, linfadenopatia, astenia, artralgia, mialgia, exantema, principalmente, nas zonas da face e tronco, podendo revelar-se sob a forma de meningite e meningoencefalite. Os sintomas decorrem do facto de, nesta fase, se atingir o pico máximo de carga vírica, com consequente aumento do risco de transmissibilidade, e uma diminuição acentuada das células T CD4⁺.

Nos meses seguintes, desencadeiam-se dois tipos de respostas - uma resposta celular, com aumento do número de linfócitos T CD8⁺, e uma resposta humoral, com o aparecimento de anticorpos anti-VIH (seroconversão) com consequente decréscimo acentuado da carga vírica para níveis que se manterão constantes, em média, nos próximos oito a doze anos. Esta fase assintomática da doença não envolve uma latência virológica, mas sim uma latência clínica com ausência de quaisquer sinais ou sintomas, coincidindo, na maioria das vezes, o diagnóstico da infecção com esta etapa.

O ataque incisivo e exaustivo aos linfócitos T CD4⁺ acaba por determinar o aparecimento da fase sintomática da doença separada em dois estádios. No período mais precoce, denominado de Complexo Relacionado com a SIDA, as patologias detectadas nas áreas dermatológica, neurológica e hematológica bem como o aparecimento de leucoplasia oral, úlceras aftosas, diarreia intermitente, fadiga, suores nocturnos, candidíases orais e vaginais não colocam ainda em risco a vida do doente.

Assim que o número de linfócitos T CD4⁺ se encontra abaixo de 200/mm³, a gravidade da situação aumenta consideravelmente, instalando-se o Síndrome de Imunodeficiência Adquirida com o aparecimento sequencial e/ou simultâneo de neoplasias e infecções oportunistas. O estado de imunossupressão do doente, o grau de virulência, a acção de fungos, parasitas e bactérias, incluindo a reactivação de microorganismos endógenos, condicionam largamente um envolvimento local ou sistémico que pode ser fatal.

Com o objectivo de melhorar a avaliação da infecção pelo VIH-1, foram criados critérios de classificação da infecção por VIH baseados na contagem de linfócitos T CD4⁺, pelo *Centers for Disease Control and Prevention* (tabela 1), e definidas as doenças que auxiliam o diagnóstico de SIDA, pela Organização Mundial de Saúde (tabela 2), sendo apresentados em seguida.

Tabela 1. Critérios de classificação da infecção por VIH, segundo o *Centers for Disease Control and Prevention* (1993).(41)

CRITÉRIOS DE CLASSIFICAÇÃO DA INFECÇÃO POR VIH		
	Categoria Clínica	
Linfócitos T CD4 ⁺ (mm ³)	A	B
≥ 500	A1	B1
200 - 499	A2	B2
< 200 (contagem indicadora de SIDA)	A3	B3

A = portador assintomático, primo-infecção, síndrome linfadenopático
B = sintomático
C = entidades definidoras de SIDA (área sombreada definidora de SIDA)

Tabela 2. Doenças definidoras do diagnóstico de SIDA, segundo a Organização Mundial de Saúde (1993).(41)

DOENÇAS DEFINIDORAS DO DIAGNÓSTICO DE SIDA

Candidíase esofágica, traqueal, brônquica ou pulmonar
Coccidioidomicose disseminada ou extrapulmonar
Cryptococose extrapulmonar
Cryptosporidiose crônica (diarreia > um mês)
Doença citomegálica, atingindo um órgão que não o fígado, baço ou gânglios e com idade > um mês
Encefalopatia ou síndrome demencial
Esofagite, bronquite e pneumonia por <i>Herpes simplex</i> com idade > um mês
Herpes mucocutâneo crônico de evolução > um mês
Histoplasmose disseminada ou extrapulmonar
Infecção disseminada ou extrapulmonar por <i>Mycobacterium avium</i> ou <i>M. kansasii</i>
Infecção extrapulmonar por <i>Mycobacterium tuberculosis</i>
Infecção por micobactérias outros tipos ou de tipos não identificados, disseminada ou extrapulmonar
Infecção pulmonar por <i>Mycobacterium tuberculosis</i> , no adulto ou adolescente
Infecções bacterianas múltiplas ou recorrentes em criança com idade < 13 anos
Isosporidiose intestinal (diarreia > um mês)
Leucoencefalopatia multifocal progressiva
Pneumonia bacteriana recorrente
Pneumonia intersticial linfóide em idade < 13 anos
Pneumonia por <i>Pneumocystis jiroveci</i>
Retinite por citomegalovírus (com perda de visão)
Septicémia por <i>Salmonella</i> não <i>typhi</i> recorrente
Síndrome de emaciação
Toxoplasmose cerebral em idade > um mês
Cancro invasivo do colo do útero
Linfomas não - <i>Hodgkin</i>
Linfoma de <i>Burkitt</i> (ou equivalente)
Linfoma imunoblástico (ou equivalente)
Linfoma primitivo do cérebro
Sarcoma de <i>Kaposi</i>

Em Portugal, é de destacar a maior frequência de aparecimento de tuberculose pulmonar e extra-pulmonar, uma infecção oportunista que pode ocorrer com qualquer contagem de linfócitos T CD4⁺, daí ser muitas vezes a pioneira no diagnóstico de SIDA; a pneumonia por *Pneumocystis jiroveci*, normalmente detectada quando o número de células CD4⁺ se encontram abaixo de 200/mm³ e manifestando-se com sintomas febris acompanhados de tosse produtiva e dispneia progressiva; o cancro invasivo do colo do útero, possibilitando o seu rastreio a detecção precoce de eventuais lesões com consequente intervenção imediata.(41)

Por tudo isto, será imprescindível o diagnóstico da infecção VIH / SIDA aquando da presença de alguma destas doenças ou perante a suspeita de algum factor ou comportamento de risco. A nível laboratorial, procede-se à detecção de anticorpos para os抗énios específicos do VIH por meio de testes imunoenzimáticos ELISA. Caso o resultado seja negativo, não se efectuam novos testes, a não ser que a exposição tenha

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ocorrido há menos de três meses, implicando a repetição passados três meses. Se o resultado fôr positivo ou indeterminado, o teste é repetido em duplicado e sujeito a confirmação com outro tipo de teste – *Western Blot*.

Outros tipos de testes utilizados são a pesquisa de ARN-VIH por PCR, com quantificação, ou de ADN-VIH por PCR, mais sensível, a pesquisa do antígeno p24 por ELISA para determinação da virémia ou, mais recentemente, o recurso a testes rápidos, fundamentalmente em situações agudas, cujos resultados devem ser considerados preliminares e, por conseguinte, sujeitos a confirmação com os testes mais sensíveis e específicos acima referidos.(6,30,40-44)

Analizando, assim, a evolução natural da infecção por VIH, salienta-se que factores como a idade, o género, a geografia, socioeconómicos e características do vírus e do hospedeiro condicionam a susceptibilidade individual ao VIH e a progressão da doença, tendo de se determinar as alternativas terapêuticas mais adequadas e qual o momento certo para as aplicar.(45)



***TERAPÊUTICA ANTI-
RETRÓVÍRICA***

Tendo em conta os passos vitais da replicação vírica(46),

- fixação do VIH à membrana da célula hospedeira e consequente libertação do conteúdo vírico para o seu interior;
- síntese de ADN a partir do ARN vírico, por acção da transcriptase reversa;
- integração do ácido nucleico recém-sintetizado no material genético da célula hospedeira, por acção da integrase;
- síntese de ARN mensageiro e tradução em poliproteínas, clivadas seguidamente pela protease, em novas proteínas víricas;
- formação de novas partículas víricas que sofrerão um último processo de maturação, aquando da libertação da célula hospedeira, que as tornarão aptas na sua função infecciosa;

e o impacto social e sanitário nunca antes visto na história da Medicina, a investigação na área da infecção VIH / SIDA avança consideravelmente com a introdução no mercado terapêutico, em 1987, do primeiro fármaco anti-retrovírico – zidovudina. Seguem-se novas descobertas de novas estratégias terapêuticas baseadas na interrupção do ciclo de vida do VIH e na imunoterapia.(46-50)

Assim, segundo a classificação ATC da Organização Mundial de Saúde, distinguem-se as seguintes classes farmacológicas:

- *inibidores da transcriptase reversa* os quais se subdividem nos compostos análogos de nucleósidos, análogos de nucleotídos e não análogos de nucleósidos

Os análogos de nucleósidos, onde se inclui o protótipo zidovudina, inibem competitivamente a enzima transcriptase reversa e podem interromper o crescimento da cadeia de ADN vírico por incorporação na mesma, exigindo, para os ditos efeitos, sucessivas fosforilações intracitoplasmáticas por enzimas celulares até adquirirem a forma trifosfatos.

Os análogos nucleotídicos, onde se destaca o tenofovir, são funcionalmente similares aos anteriores, diferindo estruturalmente no facto de serem compostos monofosfatados o que dispensa a primeira fosforilação, catalisada, geralmente, por uma enzima presente em células com infecção efectiva.

A tabela 3 resume as características farmacocinéticas dos fármacos representantes dos grupos referenciados, salientando-se as interacções farmacológicas, como potenciais indutores de resultados clínicos negativos, com antivirais (ganciclovir, valganciclovir, ribavirina), metadona, allopurinol, hidroxiureia, doxorrubicina.

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Tabela 3. Características farmacocinéticas dos inibidores da transcriptase reversa análogos de nucleósidos e nucleótidos.(50)

INIBIDORES DA TRANSCRIPTASE REVERSA ANÁLOGOS DE NUCLEÓSIDOS					
Fármaco	Distribuição	Ligação às proteínas plasmáticas	Metabolismo	Administração	Semi-vida (h)
Zidovudina	1,6 L/Kg	25-38%	Glucuronidação hepática	Com alimentos	1
Didanosina	1,08 L/Kg	<5%	Desconhecido	Estômago vazio	1,5
Emtricitabina	1,4 ± 0,3 L/Kg	<4%	Limitado; oxidação e conjugação hepáticas	Com alimentos	10
Zalcitabina	0,5 L/Kg	<4%	Fosforilação intracelular	Com alimentos	2
Lamivudina	1,3 L/Kg	<36%	5,6% de metabolito trans-sulfóxido	Com alimentos	5-7
Estavudina	0,5 L/Kg	Residual	Fosforilação intracelular com metabolito activo	Com alimentos	1-1,6
Telbivudina ^(a)	Desconhecida	3,3%	Sem influência no CYP450	Com alimentos	41,8 ± 11,8
Abacavir	0,86 L/Kg	50%	Hepático, via álcool desidrogenase e glucuronil-transferase	Com alimentos	1,5
Entecavir ^(a)	Desconhecida	13%	Glucuronidação hepática	Com alimentos	24

INIBIDORES DA TRANSCRIPTASE REVERSA ANÁLOGOS DE NUCLEÓTIDOS					
Fármaco	Distribuição	Ligação às proteínas plasmáticas	Metabolismo	Administração	Semi-vida (h)
Tenofovir	1,2-1,3 L/Kg	7%	Hidrólise intracelular	Com alimentos	17
Adefovir ^(a)	≈ 0,3 L/Kg	≤ 4%	Sem influência no CYP450	Com alimentos	7,2

^(a)Consulta dos respectivos Resumos das Características do Medicamento por falta de informação disponível na literatura referenciada.

Os análogos não nucleósidos inibem de forma não competitiva a transcriptase reversa, ligando-se directamente a esta enzima num local próximo, mas distinto do local onde se ligam os compostos anteriores, bloqueando a ADN polimerase dependente do ADN e ARN e não necessitando de qualquer fosforilação intracelular.

A tabela 4 resume as características farmacocinéticas dos seus fármacos representantes, salientando-se a descoberta de um novo fármaco (ainda não aprovado em Portugal) – etravirina – pertencente à segunda geração de análogos não nucleósidos o qual tem mostrado eficácia em situações de aparecimento de resistências a outros

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antiretrovíricos, incluídos ou não nesta classe. Este fármaco está associado a uma semi-vida longa e a uma elevada biodisponibilidade, permitindo apenas duas administrações diárias.(51-53)

Destacam-se, pela razão mencionada anteriormente, as interacções com fármacos antifúngicos (fluconazol, itraconazol, cetoconazol), anticonvulsivantes (carbamazepina, fenobarbital, fenitoína), benzodiazepinas (alprazolam, diazepam, lorazepam, midazolam, triazolam), antibacterianos (claritromicina, rifabutina, rifampicina), erva de São João, hormonas contraceptivas, antidislipidêmicos (atorvastatina, fluvastatina, lovastatina, simvastatina, pravastatina, rosuvastatina) e o anticoagulante varfarina. Particularmente, a delavirdina interage com a fluoxetina, quinidina, sildenafil, vardenafil, tadalafil e a etravirina interage com sildenafil, dexametasona e anti-arrítmicos.

Tabela 4. Características farmacocinéticas dos inibidores da transcriptase reversa não análogos de nucleósidos.(50)

INIBIDORES DA TRANSCRIPTASE INVERSA NÃO ANÁLOGOS DE NUCLEÓSIDOS						
Fármaco	Biodisp. oral	Ligaçāo às proteínas plasmáticas	Metabolismo	Eliminação	Administração	S-V (h)
Efavirenz	42%	>99%	Substrato do citocromo P450 (3A4), inibidor / induzor de CYP3A4	14-34% via renal, como metabolitos; 16-61% via fecal, sem modificações	Estômago vazio	40-55
Nevirapina	>90%	50-60%	Substrato do citocromo P450 (3A4), induzor de CYP3A4 / 2B6	90% via renal, como metabolitos, e <5% sem modificações; 10% via fecal	Com alimentos	25-30
Delavirdina	85%	98-99%	Substrato do citocromo P450 (3A4), inibidor de CYP3A4	51% via renal, como metabolitos, e <5% sem modificações; 44% via fecal	Com alimentos	5,8

Biodisp. oral = Biodisponibilidade oral
S-V = Semi-vida

- *inibidores da protease*

Introduzidos em 1995, estes fármacos inibem a enzima responsável pela clivagem das poliproteínas nas proteínas estruturais finais do cerne do vírião maduro. Como actuam numa fase pós-integração do ADN vírico no genoma da célula hospedeira, não evitam a destruição da célula infectada, mas previnem a progressão da infecção com a produção de partículas víricas isentas dessa propriedade.

A tabela 5 resume as características farmacocinéticas dos seus fármacos representantes, destacando-se, pelo motivo referido acima, as interacções farmacológicas com antifúngicos, anticonvulsivantes, antidislipidémicos e antibacterianos já referidos anteriormente, anti-ácidos, antagonistas dos receptores da histamina H₂, inibidores da bomba de protões, erva de São João, hormonas contraceptivas, benzodiazepinas (acrescentam-se às já mencionadas o oxazepam e temazepam), metadona, inibidores da fosfodiesterase (sildenafil, tadalafil, vardenafil), bloqueadores dos canais de cálcio (diltiazem). A associação darunavir e ritonavir interage especificamente com paroxetina e sertralina, enquanto o indinavir interage com sumo de toranja, o ritonavir com desipramina, trazodona e teofilina e o saquinavir com sumo de toranja e dexametasona.

Tabela 5. Características farmacocinéticas dos inibidores da protease.(50)

INIBIDORES DA PROTEASE				
Fármaco	Absorção	Ligação às proteínas plasmáticas	Metabolismo	Semi-vida (h)
Atazanavir	Aumento na presença de alimentos	86,00%	Hepático, via CYP3A4	7
Darunavir	37% (aumento na presença de ritonavir)	95,00%	Hepático, principalmente por via CYP3A	15
Amprenavir ^(a)	Diminuição na presença de alimentos	90%	Hepático via CYP3A4	7,1-10,6
Fosamprenavir	63% (aumento na presença de ritonavir)	90%	Conversão em amprenavir por fosfatases celulares; metabolismo hepático via CYP3A4	7,7
Indinavir	Diminuição na presença de refeições ricas em lípidos	60%	Hepático, via CYP3A4	1,8
Lopinavir / ritonavir	Formulação oral em comprimidos não afectada com a presença de alimentos	98-99%	Hepático, via CYP3A	5-6

INIBIDORES DA PROTEASE				
Fármaco	Absorção	Ligaçāo às proteínas plasmáticas	Metabolismo	Semi-vida (h)
Nelfinavir	Aumento de 2 a 3 vezes na presença de alimentos	98%	Hepático, via CYP2C19 e 3A4	3,5-5
Ritonavir	Variável, aumento na presença de alimentos	98-99%	Hepático, via CYP3A4 e 2D6	3-5
Saquinavir	Baixa, aumento na presença de refeições ricas em lípidos	97%	Hepático, via CYP3A4	1-2
Tipranavir	Incompleta (percentagem não estabelecida)	99%	Hepático, via CYP3A4	6

^(a)Consulta dos respectivos Resumos das Características do Medicamento por falta de informação disponível na literatura referenciada.

- *inibidores da entrada*

Denotando-se uma insuficiente clarificação da classificação ATC, tida em conta até então, relativamente à diferenciação dos inibidores da entrada, foi considerada a distinção desta classe farmacológica em inibidores da fusão, antagonistas do correceptor CCR5 e inibidores da integrase, visível no documento “Boas Práticas de Farmácia Hospitalar no âmbito da Infecção VIH / SIDA”, elaborado pela Coordenação Nacional para a Infecção VIH / SIDA, Alto Comissariado da Saúde e Ministério da Saúde.(54)

O enfuvirtide é o primeiro e único composto pertencente a esta classe dos inibidores da fusão. Semelhante ao domínio HR2 da gp41, liga-se ao domínio HR1 da mesma glicoproteína transmembranar, impedindo a ocorrência das alterações conformacionais conducentes à fusão da membrana vírica com a membrana celular.

A sua administração é obrigatoriamente feita por injecção subcutânea, sendo a sua biodisponibilidade de 84%. Este fármaco é metabolizado por hidrólise, não exerce qualquer acção sobre as isoenzimas do citocromo P450 e apresenta uma semi-vida plasmática de 3,8 horas.(50,52,55,56)

No mercado português, estão aprovadas duas novas substâncias com diferentes mecanismos de acção - o antagonista do correceptor CCR5, maraviroc, e o inibidor da integrase, raltegravir.

A descoberta do papel primordial dos receptores das quimiocinas na ligação do vírus ao hospedeiro, a detecção de defeitos na expressão de CCR5 pela célula hospedeira capazes de reduzir a infecção aguda vírica e consequente progressão da

doença e a presença do correceptor CCR5 em mais de 50% das infecções por VIH, fornecem a base sustentável para o desenvolvimento de antagonistas do CCR5. O fármaco maraviroc inibe a ligação das quimiocinas MIP1 α , MIP1 β e RANTES à membrana das células que expressam CCR5, bloqueia a emissão dos sinais emitidos pelo correceptor após a ligação das quimiocinas, prevenindo a entrada na célula hospedeira. A sua actividade anti-retrovírica decorre em concentrações muito baixas, é absorvido rapidamente e é um substrato do CYP3A4, sendo a sua excreção maioritariamente fecal, sem sofrer alterações.(55,57)

Os inibidores da integrase constituem uma nova classe de anti-retrovíricos que inibem a integração do ADN no genoma do linfócito T CD4 $^+$, ligando-se ao centro catalítico da enzima. O fármaco raltegravir tem uma absorção rápida, sendo metabolizado no fígado por glucuronidação.(52,58)

A verdadeira revolução emerge quando se percebe que, combinando, preferencialmente, três fármacos pertencentes a estas classes – terapêutica anti-retrovírica de alta eficácia, HAART(59), o resultado obtido atinge uma eficácia superior, não conducente à erradicação do vírus, mas coincidente com um controlo mais rigoroso, em termos de morbilidade e mortalidade, da evolução da doença. Esta adquire, deste modo, o seu estatuto crónico, denotando-se uma melhoria significativa do bem-estar e qualidade de vida do doente infectado.(2)

Para que o sucesso terapêutico seja a meta alcançada com a manutenção da replicação vírica em níveis abaixo do limiar de detecção e a maximização do número de linfócitos T CD4 $^+$, os referidos marcadores imunológico e virológico são preponderantes na decisão da instauração e modificação da terapêutica anti-retrovírica e profilaxia de infecções oportunistas, sendo realizada a sua avaliação periodicamente, juntamente com a monitorização de outros parâmetros laboratoriais e a realização de testes genotípicos e fenotípicos de resistência.(60)

A selecção do regime terapêutico é, então, feita individualmente, tendo em conta, para além dos aspectos referidos, factores sociais, económicos, a existência de comorbilidades como eventuais comportamentos de risco, doenças do foro psiquiátrico, doenças cardiovasculares e hepáticas, a tolerância individual, a comodidade da posologia, a simplicidade do esquema terapêutico, a detecção de potenciais interacções medicamentosas, efeitos adversos e resistências, salientando-se a educação e a participação activa do doente em todo este processo que perdurará ilimitadamente na sua vida e que exigirá uma capacidade de adesão superior a 95%.(2,61,62)

A terapêutica anti-retrovírica deve ser iniciada perante a detecção de uma infecção sintomática com uma contagem de linfócitos T CD4 $^+$ inferior a 350 células/mm 3 , sendo esta recomendação fortalecida quando a contagem de T CD4 $^+$ é inferior a 200 células/mm 3 . Por outro lado, deve ser iniciada em determinados grupos de doentes: doentes coinfetados com hepatite B (quando o tratamento para a hepatite B é indicado), doentes com nefropatia associada ao VIH, grávidas, idosos, doentes com carga vírica elevada, em situações de serodiscordância no casal e aquando de uma queda abrupta do número de células T CD4 $^+$. Quando o número de células T CD4 $^+$ é superior a

350/mm³, surgem algumas controvérsias na implementação da terapêutica(63) decorrente do balanço entre os potenciais benefícios (manutenção do número de T CD4⁺ e diminuição dos danos no sistema imunitário, diminuição do aparecimento de doenças oportunistas e não oportunistas, diminuição do risco de transmissão da infecção) e riscos associados (aumento da probabilidade de aparecimento de efeitos adversos, toxicidades e resistências conducentes a uma menor adesão ao tratamento e a possíveis perdas de futuras opções de tratamento).

Segundo as recomendações mais recentes(60,64), a tendência é o início cada vez mais precoce, atendendo à diminuição da morbidade e mortalidade demonstradas nos estudos realizados bem como o aparecimento dos novos medicamentos, mais eficazes, mais facilmente administrados e mais bem tolerados, capazes de permitirem a construção de novos esquemas terapêuticos, nomeadamente em doentes que apresentam falência ou resistência aos esquemas habituais.(50)

Para doentes que vão iniciar a terapêutica, as combinações actuais a adoptar incluem:

- um inibidor da transcriptase reversa não análogo dos nucleósidos com dois análogos nucleosídicos

ou

- um inibidor da protease (associado, de preferência, com ritonavir) com dois inibidores da transcriptase reversa análogos dos nucleósidos.

Dentro dos inibidores da transcriptase reversa não análogos dos nucleósidos, o fármaco que reúne mais consenso é o efavirenz, excepto no primeiro trimestre da gravidez e em situações de perturbações psiquiátricas, sendo a alternativa a nevirapina cujas precauções de utilização são requeridas em situações de insuficiência hepática e aquando da associação com tenofovir e emtricitabina / lamivudina devido a uma possível falência virológica.

Dentro dos inibidores da protease, as preferências recaem sobre as associações com ritonavir, pela sua capacidade de aumento dos níveis séricos do seu homólogo, reduzindo-se a frequência das administrações diárias. É o caso da co-formulação lopinavir / ritonavir a qual, quando administrada uma única vez ao dia, deve ser evitada na gravidez, principalmente no terceiro trimestre. Salientam-se ainda os fármacos atazanavir (este fármaco deve ser usado com precaução em associação com inibidores da bomba de protões, anti-ácidos e antagonistas dos receptores da histamina H₂), darunavir e fosamprenavir. Os fármacos indinavir, nelfinavir, tipranavir e ritonavir, quando isolados, não são recomendados nos regimes terapêuticos iniciais.

Dentro das combinações de dois inibidores da transcriptase reversa análogos de nucleósidos, a co-formulação tenofovir / emtricitabina é a preferida, sendo de evitar a sua associação com atazanavir (não ligado a ritonavir), e com nevirapina, pelas razões referidas anteriormente, bem como em situações de insuficiência renal. As combinações

alternativas englobam: abacavir / lamivudina (esta co-formulação é de evitar aquando da presença de hipersensibilidade ao abacavir, em situações de carga vírica muito elevada devido ao risco de falência virológica e perante um elevado risco cardiovascular); didanosina / lamivudina ou didanosina / emtricitabina (a esta combinação não se deve associar atazanavir não ligado a ritonavir, sendo também de evitar em situações de toxicidade mitocondrial como no caso de pancreatite e neuropatia periférica), zidovudina / lamivudina (a zidovudina pode influenciar a evolução de anemias e/ou neutropenias). As associações didanosina e estavudina, emtricitabina e lamivudina, estavudina e zidovudina estão contra-indicadas em qualquer regime terapêutico.

Alguns estudos mostram que combinações de três destes fármacos análogos nucleosídicos em substituição dos regimes preferidos, apesar da diminuição de efeitos adversos e interacções medicamentosas, não induzem o efeito desejado na actividade virológica, com excepção das associações abacavir / zidovudina / lamivudina e tenofovir / zidovudina / lamivudina.

Os regimes terapêuticos descritos, recomendados e alternativos, encontram-se representados na tabela 6.

Tabela 6. Regimes terapêuticos anti-retrovíricos aconselhados em doentes em início de tratamento.

REGIME TERAPÊUTICO BASEADO EM INIBIDORES DA TRANSCRIPTASE REVERSA NÃO ANÁLOGOS DE NUCLEÓSIDOS	
Recomendação	Alternativa
Efavirenz	Nevirapina
REGIME TERAPÊUTICO BASEADO EM INIBIDORES DA PROTEASE	
Recomendação	Alternativa
Atazanavir + ritonavir	Atazanavir
Darunavir + ritonavir	Fosamprenavir
Fosamprenavir + ritonavir	Saquinavir + ritonavir
Lopinavir + ritonavir	
REGIME TERAPÊUTICO BASEADO EM INIBIDORES DA TRANSCRIPTASE REVERSA ANÁLOGOS DE NUCLEÓSIDOS	
Recomendação	Alternativa
Tenofovir + emtricitabina	Abacavir + lamivudina Didanosina + (lamivudina ou emtricitabina) Zidovudina + lamivudina
	Abacavir + lamivudina + zidovudina Zidovudina + lamivudina + tenofovir

Associações quádruplas (mega HAART) com os novos fármacos enfuvirtide, etravirina, raltegravir e maraviroc já fazem parte da prática clínica dos Hospitais da Universidade de Coimbra, não existindo ainda dados suficientes acerca da sua eficácia como primeira linha da terapêutica.

Situações especiais como a infecção diagnosticada na gravidez, na infância e na adolescência requerem uma apreciação particular e redobrada com uma maior incidência na educação do doente.

Atendendo à maior vulnerabilidade da mulher à infecção por VIH, já referida, aspectos como a actividade sexual, contracepção e o estabelecimento de uma consulta de planeamento familiar têm de ser discutidos. Sendo o primeiro trimestre da gravidez o período mais crítico, a terapêutica a seguir terá de ter em consideração alterações farmacocinéticas decorrentes da situação fisiológica diferente, potenciais reacções adversas, incluindo a teratogenicidade de alguns fármacos, e o risco de transmissão perinatal, combatido, principalmente na altura do parto, com os procedimentos indicados anteriormente.(65,66)

Graças à terapêutica anti-retrovírica iniciada ou mantida durante a gestação, a mortalidade infantil por infecção por VIH diminuiu drasticamente nos países desenvolvidos, permitindo também o aumento da esperança de vida das crianças infectadas.(67)

A heterogeneidade em termos sociodemográficos, o modo de transmissão do VIH, comportamentos de risco e os estados imunológico, clínico e psicossocial nos adolescentes, equacionam a hipótese de uma monitorização terapêutica, para além da realização de mais estudos nesta faixa etária, para se perceber quais os fármacos e respectivas doses a utilizar com maior efectividade, tendo como objectivo o aumento da adesão à terapêutica.

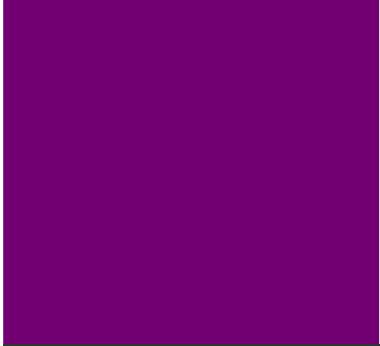
Uma população a salientar é a utilizadora de drogas injectáveis / toxicodependentes nas quais o regime terapêutico a adoptar terá que primar pela simplicidade de doses e frequência de administração, incluindo fármacos com baixo risco hepático e neuropsiquiátrico e não interactivos com a metadona, estando, muitas vezes, presente a co-infecção com os vírus das hepatites B e C.(68)

De qualquer modo, pode ocorrer uma falência do regime terapêutico instituído influenciada por factores condicionantes de uma fraca adesão tais como(69-72):

- características do doente como a idade, o sexo, o nível de literacia e outros factores sociodemográficos;
 - características da doença como a detecção de uma carga vírica elevada, um baixo número de linfócitos T CD4⁺, uma sintomatologia acentuada associada ao diagnóstico de doenças oportunistas, a presença de doenças concomitantes e respectiva medicação, o uso de drogas ilícitas;
-

- características do tratamento como início precoce da terapêutica anti-retrovírica com fármacos menos potentes e menos bem tolerados; a detecção de falências virológica e imunológica com tratamentos prévios e de resistências desenvolvidas entretanto ou aquando de mutações geradas em plena replicação vírica nos grandes “santuários” linfo-reticulares, conducentes ao aparecimento de diferentes estirpes na mesma família vírica(73,74); a complexidade dos tratamentos com várias tomas diárias de um elevado número de fármacos com ou sem a ingestão de alimentos e fluidos; o incumprimento da toma da medicação associado à não comparência nas consultas médicas e consequente carência de acompanhamento pela equipa de profissionais de saúde(75); o aparecimento de interacções medicamentosas, toxicidades e reacções adversas.

Assim, a par da continuidade de um pretendido robusto desenvolvimento farmacológico, o estabelecimento do equilíbrio entre a potência, efectividade, segurança e tolerabilidade da terapêutica instituída é crucial para o alcançar dos objectivos traçados em prol do doente.(76,77)



*REACÇÕES ADVERSAS DA
TERAPÊUTICA ANTI-
RETROVÍRICA*

Uma das apostas trabalhadas com vista a uma melhoria da adesão da terapêutica prende-se com a explanação das reacções adversas ao doente, muitas vezes, motivo de alteração ou descontinuação da terapêutica.(62,78,79) Um exemplo é a clarificação da terminologia empregue efectuada por Aronson e Ferner(13) ao distinguirem, apesar do fenómeno em causa ser o mesmo, reacção adversa de efeito adverso. Uma reacção adversa é vista sob o ponto de vista do doente, enquanto um efeito adverso é visto sob o ponto de vista do fármaco, uma vez que o doente tem uma reacção e um fármaco provoca um determinado efeito.

O aparecimento de reacções adversas pode resultar de(60,80-82):

- uma predisposição do indivíduo, como a maior propensão das mulheres para o aparecimento de síndroma de Stevens-Johnson e hepatotoxicidade, reacções características da nevirapina, ou de acidose láctica com os análogos nucleosídicos;
- factores genéticos como os associados ao aparecimento de reacções de hipersensibilidade ao abacavir;
- a presença de comorbilidades como o alcoolismo ou hepatites B e C que elevam o risco de hepatotoxicidade;
- a concomitância de outras medicações, indutoras de interacções, como a detectada com a ribavirina e didanosina, cuja toxicidade é aumentada.

A toxicidade mitocondrial, ligada principalmente aos análogos nucleosídicos (destacam-se os fármacos zidovudina, estavudina e didanosina), resulta de um mecanismo de acção secundário à inibição da transcriptase reversa – a inibição da ADN polimerase mitocondrial – que origina uma deficiente síntese de enzimas mitocondriais produtoras de energia na forma de ATP. A intensidade e a frequência dos efeitos verificados, parecem mostrar uma certa especificidade tecidual relacionada com a estrutura farmacológica de cada um dos compostos e com o mecanismo de fosforilação subjacente.

Este tipo de toxicidade, cuja detecção pode ocorrer meses após o início do regime terapêutico instituído, traduz-se no aparecimento de miopatia (mais associada à zidovudina), neuropatia periférica, esteatose hepática e acidose láctica e pancreatite (mais associada à didanosina).

Inicialmente, surgem sintomas gastrintestinais como náuseas, anorexia, perda de peso, vômitos e dores abdominais. Estes podem evoluir para sintomas mais específicos como a fadiga, mialgias, fraqueza muscular, característicos de uma miopatia, para perturbações, ou mesmo, perda de sensibilidade nos dedos e pés e arreflexia, manifestados na presença de uma neuropatia periférica. Podem também progredir, muitas vezes de forma fatal, para insuficiência respiratória, encefalopatia, pancreatite (esta última mais frequente em situações de antecedentes de alcoolismo e de

pancreatite, num estado avançado da infecção por VIH ou perante uma associação com fármacos com toxicidade pancreática), esteatose hepática e acidose láctica.

A função hepática dos doentes submetidos a terapêutica com estes fármacos deve ser avaliada e monitorizada regularmente. Aquando do aparecimento destas reacções, equaciona-se a descontinuação do(s) fármaco(s) ou a substituição por outros análogos nucleosídicos menos propensos a toxicidade mitocondrial, sendo importante uma adequada hidratação e, nalguns casos, o recurso a fármacos como tiamina e riboflavina que mostraram uma rápida diminuição dos níveis de lactato.(84)

Dependendo da dose de zidovudina e da duração do tratamento, a toxicidade mitocondrial associada a este fármaco manifesta-se a nível hematológico com a detecção de macrocitose, anemia, neutropenia, trombocitopenia e diminuição das células precursoras hematopoiéticas.

O fármaco tenofovir mostrou, dependendo da dose e da duração do tratamento, nefrotoxicidade como a sua principal reacção adversa, caracterizada por nefropatia tubular renal e/ou nefrite intersticial (síndroma de Fanconi) com aumento dos níveis de creatinina.

As complicações dermatológicas decorrentes da terapêutica anti-retrovírica sobressaem no campo das reacções adversas.

As reacções de hipersensibilidade ao abacavir, com uma maior predisposição genética em indivíduos com o haplótipo HLA-B5701, surgem logo nas primeiras semanas de tratamento, manifestando-se com febre associada a mal-estar geral, náuseas, vômitos, exantema generalizado e obrigando à suspensão imediata do tratamento sem qualquer hipótese de reintrodução.

A descontinuação do tratamento também se verifica com o fármaco enfuvirtide ao qual se associam reacções de hipersensibilidade detectadas logo nos primeiros dias de tratamento nos locais de administração das injecções subcutâneas, sendo minimizadas com a rotação do local de aplicação ou com o recurso a um injector desenvolvido para o efeito.

Disfunções cutâneas a nível capilar e nas unhas foram atribuídas ao emprego do inibidor da protease indinavir, suspeitando-se da interacção deste fármaco com compostos retinóides. Outras reacções, também características deste fármaco, são a litíase renal, combatida com a ingestão acrescida de fluidos, e a hiperbilirrubinémia conjugada, não representativa de toxicidade hepática.

Ainda que a responsabilidade possa ser de qualquer um dos análogos não nucleosídicos, o risco de aparecimento de exantema maculopapular e eritematoso, com ou sem prurido associado e abrangendo o tronco, face e membros, com carácter evolutivo para formas mais graves como o síndroma de Stevens-Johnson e necrólise epidérmica tóxica, aumenta nos doentes tratados com nevirapina; logo, as estratégias adoptadas para diminuir a sua incidência englobam o início do tratamento com uma

dose mais baixa de nevirapina e a prescrição, controversa na opinião de alguns, de corticosteróides e anti-histamínicos, evitando-se a substituição da mesma por outro fármaco do mesmo grupo.(85)

Durante o tratamento com nevirapina e, em menor escala, com efavirenz, pode ocorrer uma elevação dos níveis de transaminases, conducente a hepatotoxicidade, a qual assume maiores proporções quando existe uma co-infecção com os vírus da hepatite B e C, exigindo uma monitorização regular. Náuseas, vômitos, mialgias, fadiga, dores abdominais e febre são os sintomas iniciais que podem estar associados a rash cutâneo, constituindo o síndrome DRESS, ou mesmo progredir para uma hepatite fulminante.

Ainda acerca dos análogos não nucleosídicos, a administração de efavirenz pode originar algumas reacções no Sistema Nervoso Central logo com as primeiras doses, que incluem perturbações da atenção e da concentração, cefaleias, vertigens, insónias, sonolência, pesadelos, agitação, alucinações, condutas desadequadas, depressão aguda grave, psicoses, exacerbação de doenças psiquiátricas diagnosticadas e ideias suicidas. As soluções a seguir passam pela administração do fármaco ao deitar com o estômago vazio, embora os sintomas tendam a diminuir e mesmo a desaparecer ao fim de algum tempo.(86)

A melhoria da função imunitária, a supressão virológica e a consequente longevidade dos doentes infectados por VIH, características da terapêutica anti-retrovírica de alta eficácia, acarretam uma das principais reacções adversas – as alterações metabólicas – que englobam hiperlipidemias, a insulino-resistência e Diabetes *Mellitus* e lipodistrofia, cuja incidência se tenta minimizar com a selecção do tratamento inicial mais adequado e com eventuais modificações ao longo do tempo.(87)

As hiperlipidemias envolvem uma elevação dos níveis das LDL e VLDL, do colesterol total, dos triglicerídeos e uma diminuição dos níveis das HDL, donde resulta um aumento do risco de doença cardiovascular, como enfarte de miocárdio e acidentes vasculares cerebrais. Estudos levados a cabo, mostram que o aumento do risco relativo de enfarte de miocárdio está associado, para além de certos factores como a idade, o género, a raça, a presença de Diabetes e de hipertensão, ao emprego de inibidores de protease que induzem o aumento dos valores de colesterol e triglicerídeos.(92)

A insulino-resistência surge quando se verifica uma actividade reduzida da insulina circulante no transporte da glicose para o interior das células, contribuindo, possivelmente, para este facto, uma inibição directa do transportador de glicose GLUT-4 e outros mecanismos também relacionados com a lipotoxicidade de ácidos gordos circulantes que interferem na cascata de reacções desencadeada com a ligação da insulina à célula. De acordo com Samaras(91), a resistência à insulina é um estado fisiopatológico que engloba uma história familiar de Diabetes tipo 2 ou uma doença cardiovascular, dados clínicos relativos a obesidade abdominal e hipertensão e a presença de distúrbios no metabolismo da glicose e hiperlipidemias. Nalguns casos, os sintomas detectados incluem poliúria, visão turva, polidipsia, polifagia, fraqueza, perda

Capítulo I

de peso e hiperglicémias mais acentuadas, quando a Diabetes já está instalada.(84,91,93-95)

A lipodistrofia consiste num síndroma caracterizado por uma redistribuição anormal da gordura corporal, com depleção ao nível da face, nádegas e extremidades (lipoatrofia) ou acumulação nas zonas dorsocervical, visceral e mamas (lipohipertrofia).

Sendo a lipoatrofia a situação mais comum nos doentes infectados, os factores de risco subjacentes prendem-se com a idade avançada, a presença de hipertrigliceridémia, o estado avançado da infecção por VIH, um número baixo de linfócitos T CD4⁺, um baixo índice de massa corporal e a existência de polimorfismos do factor de necrose tumoral α .(85,96)

Alterações na expressão e secreção das interleucinas IL-1 β e IL-6, do factor de necrose tumoral α e de adiponectina com influência na diferenciação de linhas celulares de adipócitos foram detectadas sob a acção de inibidores da protease e análogos nucleosídicos como a estavudina.(91,97)

Os distúrbios lipídicos e glucídicos, a hipertensão, a obesidade visceral e o aumento do índice de massa corporal, uma predisposição genética para desregulações metabólicas com o aumento do risco cardiovascular aglomeram-se no síndroma metabólico. Num doente infectado submetido à terapêutica anti-retrovírica, a este síndroma ainda se associam o aumento dos níveis da proteína C reactiva, baixos níveis de adiponectina e um aumento da carga vírica. Esta junção de toxicidades implica, deste modo, modificações do estilo de vida como a cessação tabágica, a perda de peso com uma alimentação variada e equilibrada, a prática regular de exercício físico, bem como, prováveis alterações terapêuticas, quer de fármacos anti-retrovíricos, dependendo do estádio da infecção, quer de outras medicações como antidiásporínicos, atendendo às interacções entre os dois grupos farmacológicos.(88,91,94)

Associados aos inibidores da protease, podem surgir fenómenos hemorrágicos, mais intensos em hemofílicos, complicações reumáticas como a osteoporose e osteopenia, manifestadas sob a forma de necrose da anca e fémur e aumento do risco de fracturas(98), e intolerância gastrintestinal, cujos sintomas mais comuns são a diarreia, vômitos, náuseas e dor abdominal.

Em relação aos fármacos mais recentes no mercado, os dados disponíveis mostram que o maraviroc pode produzir alguma diarreia, náuseas, cefaleias, tosse, tonturas, parestesias, distúrbios do sono, astenia, perda de peso, enquanto o raltegravir pode provocar dor abdominal, flatulência, lipodistrofia, astenia, artralgia e prurido(83). Os estudos realizados com a etravirina mostram que o rash cutâneo é a manifestação mais comum.(51)

O reconhecimento, o tratamento com o regime e doses adequados e a prevenção das reacções adversas são, neste modo, um ponto-chave no processo de adesão do doente à terapêutica anti-retrovírica.(99)

CAPÍTULO II



***MEDICINA BASEADA NA
EVIDÊNCIA***

Capítulo II

Desde a década de setenta do século passado e com os avanços científicos verificados que os profissionais de saúde se têm debruçado sobre a Medicina Baseada na Evidência.

Este conceito estendeu-se a outros campos da saúde, como a farmácia(100,101), a enfermagem(102-104), a radiologia(105), a fisioterapia(106), surgindo também a designação de Prática Baseada na Evidência.

A disponibilidade cada vez maior de informação na literatura(107,108) aumentou as expectativas dos consumidores em relação às recomendações levadas a cabo pelos profissionais, sofrendo o equilíbrio ciência – arte alguma “instabilidade” com a importância conferida ao lado científico da informação para além do saber e da intuição de cada profissional.

O médico britânico Archie Cochrane, tendo em conta a sua experiência com doentes, advoga a integração da prática médica com a pesquisa científica através do recurso a ensaios clínicos aleatorizados para avaliação dos métodos de tratamento, sendo o pioneiro na utilização de revisões sistemáticas e meta-análises na Medicina. Por outro lado, a publicação, por um grupo de médicos britânicos, de uma revisão da “evidência” sobre a efectividade de cuidados de saúde na gravidez e infância, reforça a necessidade de sistematizar a melhor informação disponível para a tomada de decisões clínicas.

Entretanto, a Universidade de McMaster, no Canadá, integra pela primeira vez este novo conceito nos planos curriculares de educação médica, como indutor de modernização dos serviços de saúde, centrados nas pessoas. Salienta-se também a influência, para a aplicação deste conceito, do desenvolvimento da tecnologia informática e da Internet, demonstrado na capacidade de processamento de bases de dados, no armazenamento compacto e no rápido acesso à informação pretendida.(109)

O conceito de Medicina Baseada na Evidência aparece, então, definido como “o uso consciente, explícito e criterioso da evidência científica actualizada na tomada de decisões clínicas referentes ao doente individual”.(110) Trata-se de uma conjugação entre a experiência e capacidade clínicas (evidência interna) e a busca da melhor e mais relevante bibliografia fornecida pela investigação clínica (evidência externa), com resultados frutíferos na precisão e exactidão de diagnósticos, na avaliação do prognóstico e na eficácia e segurança dos regimes terapêuticos daquele doente que, com as suas preocupações, preferências, expectativas, assume um papel activo no processo de decisão.(110-113)

Considerado um paradigma por uns(111-116), e uma moda por outros(117), os relatos antigos da associação da redução da mortalidade à prática de técnicas de assepsia, como a lavagem das mãos, são um exemplo, entre outros, da aplicação deste conceito no quotidiano clínico mais remoto.(118)

A visão simplista(108) de uma boa prática clínica, baseada nos conhecimentos técnicos adquiridos e aplicados na recolha da máxima informação para a obtenção da

história clínica completa e na realização de um cuidadoso exame objectivo(117), é alterada em prol de uma melhor qualidade dos cuidados de saúde prestados com uma possível uniformização de procedimentos.(119) Assim, as dúvidas clínicas, surgidas com o número crescente de consultas diárias(110-113,120,121), determinam a procura, no momento, da evidência existente, especializada, rigorosa e regularmente avaliada, em substituição do recurso ao colega do lado ou do manual estandardizado dos tempos da faculdade.

Deste modo, a creditação da evidência científica encontra, no seu caminho, algumas barreiras difíceis de superar:

- *a desactualização do conhecimento biomédico e a não obtenção de informação relevante em determinadas circunstâncias*, condicionadas pela falta de tempo e pelos avanços científicos, prováveis modificadores da prática clínica dos quais o profissional apenas pretende extrair o que necessita para a sua actividade diária, não colmatadas com a frequência de programas de Educação Médica Contínua, conducentes a uma prática mais deteriorada(11-113,122);
- *a exclusão de certos aspectos mais relacionados com a parte humana do profissional*, determinantes na sua competência e julgamento clínicos, que, obrigatoriamente, têm de fazer sobressair, na relação profissional – doente, um sentimento de confiança e cooperação, sem relutâncias, facilitador na toma da decisão e consequente resolução do problema - a aceitação da dúvida, a limitação dos seus conhecimentos, muitas vezes, a sua falta de experiência, o controlo das emoções sem prepotência, arrogância e superioridade, o saber ouvir, “ler” o doente e responder às suas preferências, necessidades e angústias(123-125);
- *a falta de iniciativa pessoal, a institucionalização de uma certa cultura clínica sem dinâmica de grupo*(126), a rotina quotidiana relativa “à forma como as coisas são feitas”, a constante pressão de prestação de serviços, centrados no doente, no mínimo tempo possível, associada a constrangimentos no recrutamento e fixação de recursos humanos, equipamento e financiamentos(118);
- *desconhecimento das bases da evidência* e, ainda, a detecção de grandes hiatos para se saber o que é certo fazer, a quem se aplica, o percurso a seguir, discernindo a evidência pretendida do aglomerado de publicações e, nessa, estudar a sua solidez de forma a poder aplicá-la clara e cuidadosamente; assim, a intervenção, as situações e o contexto em que a investigação é conduzida devem ser tão próximas da realidade quanto possível.(122,127-129)

Embora certas instituições universitárias e hospitalares disponham de Serviços de Informação dotados de recursos humanos especializados e de um conteúdo bibliográfico abrangente(122), tendo-se esta actividade alargado ao mundo *online*(130,131) onde fornece, em suporte documental, a informação solicitada pelos seus utilizadores, é fundamental a aquisição das capacidades e ferramentas necessárias à

localização, avaliação e aplicação da evidência. Dessa forma, o resultado final reflecte-se em mudanças a nível do diagnóstico, da terapêutica, do aconselhamento médico, da redução do tempo de estadia hospitalar, com a consequente diminuição da morbilidade e mortalidade dos doentes e a melhoria da sua qualidade de vida.(122,132)

Para dar a informação certa no tempo certo, a Medicina Baseada na Evidência, na prática, adquire um carácter cíclico, como se mostra na figura 3.

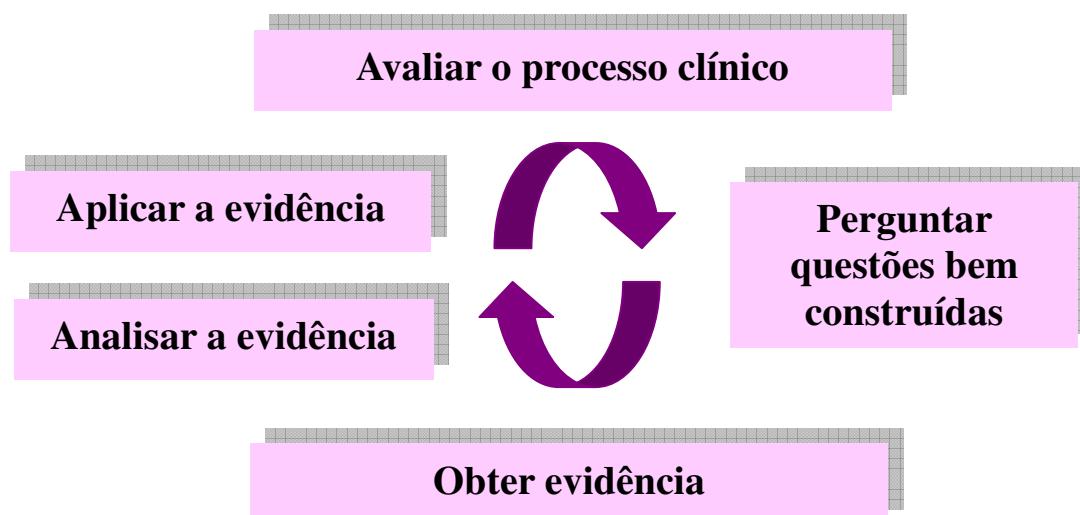


Figura 3. A Medicina Baseada na Evidência, na prática.(133)

Assim, a partir de um determinado cenário clínico, as necessidades de informação são convertidas na formulação de uma questão devidamente focada no problema em causa, procurando-se a melhor evidência disponível que será avaliada de acordo com a sua validade, relevância e tempo requerido na sua busca para aplicação dos resultados obtidos naquele doente particular, tal como a figura 4 demonstra.



Figura 4. Os passos a seguir na prática da Medicina Baseada na Evidência.(134)

Formulação da questão clínica

A incerteza sobre o modo de acção, a falta de conhecimento ou controvérsia sobre um procedimento ou terapêutica, o surgimento de resultados inesperados no doente, a prática tradicional ou as sugestões dos doentes, constituem necessidades de informação, por vezes, não muito claras, mas que, quando percepcionadas, têm de ser satisfeitas.

Para tal, o ponto-chave de todo este processo reside na formulação cuidada e clarificada da questão clínica que orientará cada um dos passos subsequentes de forma a incorporar a melhor evidência na toma da decisão final. Uma questão mal formulada é responsável pelas dificuldades encontradas no progresso da investigação, como se comprova com os seguintes aspectos a ter em conta:

- pesquisa da evidência relevante

A questão não devidamente focalizada no problema conduz à obtenção de um maior número de referências bibliográficas sem relevância, o que implica mais tempo na procura da informação pretendida.

- selecção da melhor evidência

Com a questão formulada, é possível identificar a evidência científica que forneça a resposta mais adequada à situação. A qualidade da evidência encontra-se hierarquizada, preferindo-se aquela que se encontra no topo da hierarquia, o que não significa que não se tenha de recorrer à que se encontra na base, quando não existe evidência disponível de melhor qualidade.

- aplicação da evidência

Seguindo os passos estipulados, cabe ao profissional a apreciação dos resultados obtidos, com integração da melhor evidência interna, para aplicação no seu doente, uma vez que, provavelmente não existirá uma coincidência absoluta entre o que a evidência fornece e as características da situação.(135)

A importância deste passo que tem de focar directamente o problema em causa com vista a facilitar a procura de uma resposta precisa, requer prática para a sua formulação. Nesse sentido, o recurso a uma estratégia metodológica, que defina os componentes essenciais a considerar na formulação da questão, optimiza o processo de localização da informação.

A estrutura metodológica tem como referência o modelo PICO (“*Patient or Population / Problem*”; “*Intervention*”, “*Comparison*”, “*Outcomes*”). A aplicação deste modelo permite focalizar a questão em quatro componentes principais:

- os dados, bem explícitos, sobre o doente ou população envolvidos, como a idade, o sexo, o tipo de doença, a sua gravidade, eventuais comorbilidades, dos quais se concluirá se os resultados obtidos para uma população mais alargada podem ser aplicados àquele doente específico;

- a intervenção levada a cabo, descrita com clareza e objectividade – uma exposição, um método de diagnóstico, um prognóstico, um tratamento;
- uma outra intervenção que sirva como termo de comparação com a anterior, dependendo da questão;
- os resultados clínicos importantes daí obtidos.(123,136,137)

Foi sugerida uma extensão da sigla PICO para PICOTT quando são adicionadas informações relativas ao tipo de questão (terapêutica, etiologia, diagnóstico, prognóstico) e ao tipo de estudo (ensaios clínicos controlados aleatorizados, revisões sistemáticas, meta-análises, estudos de coorte, estudos de casos – controlo, etc.), aumentando a complexidade das estratégias de pesquisa construídas e, por conseguinte, a exactidão e precisão da informação pesquisada.(138)

Pesquisa e selecção de evidência científica

Atendendo ao elevado número de publicações gerais e especializadas que impossibilitam a pesquisa manual, a uma vasta coleção de informação disponível na Internet, não sujeita a controlo da qualidade e a qualquer regulamentação, às constrições de tempo e de pessoas envolvidas na pesquisa e eventuais dificuldades subjacentes, o aparecimento, em vários formatos, de bases de dados que reúnem os artigos pertencentes ao mesmo assunto específico, tem facilitado a procura da melhor literatura, na busca da solução apropriada para a situação clínica em causa.

Estas fontes de informação devem ser seleccionadas de acordo com a sua utilidade, definida com base na sua validade ou rigor científico, na sua relevância, ou seja, na avaliação directa da efectividade dos cuidados médicos prestados ao doente, e no trabalho e tempo requeridos, pretendendo-se obter uma informação o mais válida e relevante, no mínimo espaço de tempo e com o mínimo esforço dispendido.(122,139)

Nesse sentido, a obtenção de uma maior credibilidade da informação necessária para aquele doente, num dado momento, em bases de dados bibliográficas, acessíveis electronicamente e sujeitas ou não a subscrição(140), originou a hierarquização destas fontes de informação nas seguintes categorias(141,142):

- “sistemas computorizados de suporte à decisão”, que pretendem compilar mais informação com a conjugação da informação relativa às características individuais de cada doente com a melhor evidência pesquisada para o efeito, encontrando-se, por isso, em fase de desenvolvimento;
- “sumários”, fontes integradoras da melhor evidência disponível, geradoras de uma maior dimensão de evidência que envolva as opções de gestão de um determinado problema de saúde; a Clinical Evidence, disponível em www.clinicalevidence.com, é um exemplo;

- “sinopses”, descrições sucintas de artigos originais ou revisões individuais, como a revista *American College of Physicians Journal Club* (*ACP Journal Club*) que avalia criticamente os artigos inseridos;
- “sínteses” que incluem revisões sistemáticas com informação mais detalhada como, por exemplo, a colecção de bases de dados independentes da *Cochrane Library*, produzidas pela *Cochrane Collaboration* e compostas por revisões sistemáticas e meta-análises sujeitas a uma selecção, actualização e avaliação mediante critérios rigorosos previamente definidos: a *Cochrane Database of Systematic Reviews* (CDSR), que contém revisões sistemáticas, em texto integral, de ensaios clínicos controlados aleatorizados, a *Database of Abstracts of Reviews of Effectiveness* (DARE), que contém revisões sistemáticas sobre a efectividade dos medicamentos, a *Cochrane Controlled Trials Registry* (CCTR), que contém ensaios clínicos controlados aleatorizados, a *Cochrane Review Methodology Database* (CRMD), que aborda metodologias de revisões sistemáticas, entre outras;
- “estudos originais” que abordam aspectos específicos da gestão do problema, sendo o próprio profissional de saúde o avaliador da evidência encontrada; para facilidade de consulta, estes estudos são indexados em bases de dados bibliográficas, mais extensas, como a EMBASE, uma base de dados de artigos de Medicina produzida na Europa, a *Cumulative Index of Nursing and Allied Health Literature* (CINAHL), uma base de dados de artigos de enfermagem produzida nos Estados Unidos, e a MEDLINE.(111-113,120,134,143,144)

Embora todas as fontes de informação sejam imprescindíveis no fornecimento das respostas às mais variadas questões(121), a análise da sua utilidade e fiabilidade estabelece o início da pesquisa da evidência pelo nível mais elevado, ocupando os “sumários” o lugar de destaque, com a integração da informação contida nas sinopses, sínteses e estudos originais, descendo-se na hierarquia até se encontrar suficiente informação para responder à questão clínica.

A MEDLINE, criada pela *United States National Library of Medicine*, é a base de dados bibliográfica de acesso gratuito na Internet através do operador PubMed (“*Public Medicine*”), mais largamente utilizada, obrigando o seu tamanho, de milhões de referências indexadas, à aplicação de técnicas e capacidades de pesquisa da evidência relevante, tentando evitar a perda de estudos chave e/ou a recuperação de artigos de baixa qualidade. Para o efeito, há que ter em consideração certas orientações na condução do processo de pesquisa:

- preparação da pesquisa com a criação de uma listagem de palavras Estando devidamente clarificados os componentes da questão clínica, procede-se a uma recolha de um conjunto o mais abrangente possível de palavras descriptivas de cada componente, como termos, no singular e plural, sinónimos, expressões, abreviaturas (neste caso, há que ter algum cuidado no seu emprego devido à ligação a terminologias diferentes).

- estudo das ferramentas de pesquisa disponíveis na base de dados

A MEDLINE disponibiliza um conjunto de palavras-chave indexadas ou atribuídas a cada artigo incluído na base de dados pelos respectivos indexadores. Com isto, a pesquisa é facilitada, visto utilizar-se o termo indexado adequado, ao invés de um conjunto de termos possíveis de descrição de um componente da questão; por outro lado, a especificidade obtida com o recurso a estes termos pode significar a perda de artigos relevantes que façam menção ao assunto sem que tenham sido objecto de indexação.

O conjunto de todos estes termos indexados formam um léxico designado de *Medical Subject Headings* (MeSH) o qual, devido à sua complexidade, se encontra ordenado hierarquicamente, numa estrutura em árvore, em áreas por diferentes assuntos, iniciando-se com termos mais latos ou gerais e terminando com termos mais específicos ou restritos. Um exemplo é a introdução do termo VIH, em 1988, seguida da adição, um ano mais tarde, dos termos VIH-1 e VIH-2 que permite uma pesquisa mais específica.(145)

Os “*subheadings*” consistem em termos relativos a categorias como a prevenção, o diagnóstico, reacções adversas, prognóstico ou epidemiologia, que aumentam ou a precisão do termo MeSH, quando anexado ao mesmo, ou a especificidade da pesquisa, quando se pretende focar um determinado aspecto, sendo escolhidos, para o efeito, os considerados mais apropriados.

Outras ferramentas disponíveis pela base de dados ajudam a refinar a pesquisa a efectuar.

As combinações das palavras e/ou expressões são feitas recorrendo aos operadores booleanos AND, OR e NOT. A utilização do operador AND combina as palavras e/ou expressões para que todas surjam nos artigos obtidos pela pesquisa. Com o operador OR, os artigos contêm umas, outras ou todas as palavras e/ou expressões da estratégia. O operador NOT permite a exclusão de certas palavras e/ou expressões específicas, fazendo com que os artigos que as contenham não sejam identificados o que pode levar à omissão inadvertida de artigos relevantes.

Pode ainda recorrer-se ao símbolo do corte, colocado junto às primeiras letras de uma palavra, para evitar a escrita das várias terminologias da mesma.

- construção da estratégia de pesquisa e obtenção dos resultados da pesquisa

Com todos os elementos pretendidos reunidos segundo a ordem de combinação estipulada para a situação em causa, procede-se à construção da estratégia de pesquisa com as palavras e expressões recolhidas e/ou com o vocabulário MeSH, relativas aos componentes PICO. Com a inclusão da estratégia de pesquisa na base de dados em campo próprio, é aconselhável o registo de todos os passos efectuados, possibilitando a MEDLINE a “conservação” de todo o historial da pesquisa que poderá ser consultado futuramente.

Sendo o objectivo da pesquisa encontrar a informação mais útil e minimizar os artigos irrelevantes, nem sempre isto se verifica, podendo obter-se um elevado número de artigos o que implica a necessidade de reformular a estratégia de pesquisa com a substituição de palavras, expressões ou vocabulário MeSH mais preciso e subtítulos mais específicos ou mesmo a introdução de limites específicos, disponíveis na base de dados, como o ano e tipo de publicação, a faixa etária, a língua, o autor, o periódico, o assunto, etc. A obtenção de um baixo número de artigos pode ser devida à falta de informação disponível, podendo ser alargada com o inconveniente da alteração da sua precisão.(132,134,144,146-150)

Análise crítica da evidência científica

Qualidade, relevância e aplicabilidade são características a ter em conta na apreciação crítica da evidência para responder a uma determinada questão formulada.

As ferramentas usadas nesta etapa do processo consistem num conjunto de questões estruturadas e detalhadas, para cada tipo de questão, que funcionam como critérios de avaliação da qualidade da condução do estudo, da recolha de informação e da utilidade e aplicabilidade dos resultados obtidos ao doente em causa. Isto significa que, tendo sempre em mente que a evidência científica é o produto de uma investigação bem desenhada e bem controlada, a sua apreciação crítica resume-se a três questões chave – é a qualidade do estudo suficientemente boa para usar os resultados?; são os resultados aplicáveis ao contexto em causa?; o que significam os resultados para aquele doente?. A primeira questão centra-se na análise do desenho, métodos e forma como o estudo foi conduzido de modo a gerar resultados imparciais, sem enviesamentos, enquanto a segunda questão se direciona para a análise da aplicabilidade e a terceira questão para o reflexo da interpretação dos resultados na satisfação das necessidades do doente.

Com o objectivo de minimizar o enviesamento, aplica-se a noção de hierarquia da evidência, explicada atrás, ao tipo de estudo em análise.

A figura 5 mostra, sob a forma de uma pirâmide, que, à medida que se progride da base para o topo, o número de estudos e consequente quantidade de literatura disponível diminui, ao mesmo tempo que a relevância da informação obtida aumenta, embora cada nível da hierarquia contribua para o conhecimento total. Todos os estudos devem ser consultados para efeitos de complementaridade, diversidade ou contraposição de informação com vista à obtenção da informação mais relevante que pode ser encontrada em qualquer situação.(142)

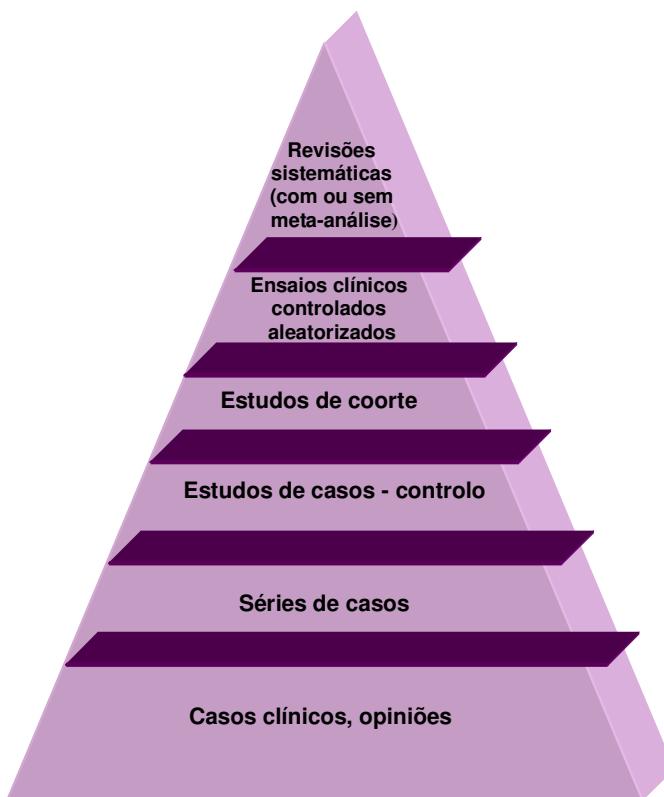


Figura 6. A hierarquia da evidência.(151)

O interesse crescente em revisões sistemáticas como sínteses de evidência, decorre da quantidade de informação publicada conducentes a dificuldades de acessibilidade por parte dos profissionais, bem como a exigências de tempo na busca da solução apropriada e a dificuldades na compreensão das conclusões de estudos relevantes.

Nesse sentido, a maioria das revisões sistemáticas, que pretendem fornecer a informação relevante em áreas clínicas específicas, têm sido desenhadas com ensaios clínicos controlados, com intervenções distintas. Archie Cochrane, em 1979, chamava a atenção para a necessidade da existência de “um sumário crítico organizado, por especialidade ou sub-especialidade, actualizado periodicamente, com todos os ensaios aleatorizados controlados relevantes”.(152)

A interferência humana constatada com uma opinião tendenciosa sobre determinado assunto, ou a falta de investimento pessoal na apreciação de evidência trabalhada previamente por parte de revisores reconhecidos na área, a globalização da pesquisa de forma a incluir estudos ainda não publicados ou publicações noutras línguas que não o inglês para não enviesar os resultados, levaram a que se delineassem estratégias na elaboração de revisões sistemáticas.

Definidos claramente os objectivos e hipóteses com que lidará o revisor, este decide os estudos que irá incluir, segundo determinados critérios explícitos de inclusão e exclusão e mediante as características do estudo como o seu desenho e o tipo de participantes, intervenções e resultados. Segue-se a pesquisa global de todas as fontes relevantes e a verificação se os artigos recuperados cumprem os critérios de elegibilidade estabelecidos no passo anterior, processo este efectuado individualmente por mais de um revisor para comparação dos resultados. As características dos estudos que passarão a incluir a revisão são sujeitas a tabulação, como demonstração da concordância entre os revisores, embora as razões de exclusão dos outros artigos tenham de ser explicadas. A qualidade metodológica dos artigos incluídos também é analisada por mais de um revisor, com recurso a um sistema de classificação ou a um conjunto de questões estruturadas, de um modo não enviesado perceptível aquando da coincidência destes resultados com os obtidos com a análise de estudos de todos os padrões de qualidade. A finalização deste processo ocorre com a extracção dos dados, com a exposição das medições feitas e a sua análise estatística, sendo, por conseguinte, as conclusões suportadas pelos resultados.

Consideradas o padrão de ouro na apreciação da eficácia de um tratamento ou intervenção, a qualidade dos métodos utilizados na identificação, apreciação e sistematização da evidência, diferença crucial entre as revisões sistemáticas e as revisões narrativas tradicionais, deve ser avaliada com o cumprimento dos aspectos relacionados com a clareza da finalidade da revisão, com a exposição de uma estratégia de pesquisa sistemática e global, identificativa dos estudos relevantes, com a expressão dos critérios de inclusão e exclusão dos estudos e, consequentemente, se a selecção dos mesmos não foi enviesada, com a apreciação da qualidade dos estudos incluídos, com a combinação sistemática dos resultados dos estudos obtidos e com a fundamentação das conclusões com os dados.(152)

A meta-análise envolve a combinação das análises estatísticas efectuadas com os resultados obtidos em estudos elaborados nos mesmos moldes, incluídos em revisões sistemáticas. À custa da meta-análise, pode determinar-se se a intervenção em causa tem um efeito benéfico ou prejudicial e qual a dimensão do mesmo. Para isso, há que ter em consideração certos conceitos estatísticos:

- risco relativo, definido como a proporção entre o risco no grupo de intervenção e o risco no grupo controlo, entendendo-se por risco a razão entre o número de indivíduos com determinada característica de um grupo e o total de indivíduos desse grupo;
- razão de probabilidade, definida como a comparação entre a probabilidade de ocorrência de um evento no grupo de tratamento, com a probabilidade de ocorrência do mesmo evento no grupo controlo, entendendo-se por probabilidade a razão entre o número de indivíduos de um grupo onde ocorreu determinado evento e o número de indivíduos onde o evento não ocorreu;
- intervalo de confiança, com uma amplitude de 95%, definido como uma expressão da precisão da estimativa do risco relativo ou razão de probabilidade.

Assim, com as revisões sistemáticas disponíveis, autênticas sínteses reproduutíveis das informações sobre determinado tópico, e o poder estatístico das meta-análises, evita-se uma duplicação de esforços na pesquisa e apreciação da evidência com a certeza do seu rigor, crítica e avaliação periódicas.

Relembrando o delineamento do processo de apreciação crítica da evidência, o tipo de questão formulada determina a escolha do tipo de estudo mais apropriado, mais preciso e menos enviesado, sendo a sua qualidade apreciada mediante critérios específicos relativos ao seu desenho, amostra da população, medidas utilizadas, características do investigador, colheita e análise dos dados.

Perante uma questão sobre uma terapêutica ou intervenção, a escolha recai sobre um ensaio comparativo / prospectivo, idealmente controlado e aleatorizado com ocultação da dita aleatoriedade até ocorrer a distribuição o que traduz o rigor da sua condução.

Na apreciação da qualidade do estudo, devem ter-se em consideração determinados aspectos:

- a distribuição aleatória da amostra para o grupo de controlo ou de intervenção, assegurando-se, tanto quanto possível, a semelhança entre os grupos para que a diferença nos resultados seja devida somente à intervenção; de acrescentar a importância do conhecimento de certos detalhes relativos à demografia e estado de saúde dos indivíduos pertencentes aos dois grupos como, por exemplo, idade, presença de comorbilidades, gravidade da doença;
- ocultação aos investigadores, doentes e clínicos do grupo onde se encontra inserido o doente, para evitar enviesamentos dos resultados provocados por alterações de comportamentos face à situação; a ocultação pode abranger um grupo (ocultação única) ou todos os grupos intervenientes (ocultação dupla / tripla);
- fornecimento detalhado da intervenção para futura reproducibilidade, bem como dos instrumentos de medida e resultados;
- abandono, por parte dos participantes, dos ensaios por morte, não adesão ao tratamento, efeitos adversos do tratamento, etc., devendo as razões ser devidamente investigadas no sentido da sua influência nos resultados.

Este tipo de estudo, no qual se busca um controlo de todas as variáveis, tende a ser caro e longo, impossibilitando, muitas vezes, o rigor subjacente à generalização dos resultados.

Uma questão relativa à eficácia de um teste de diagnóstico ou de um método de apreciação requer um estudo transversal, habitualmente gerador de hipóteses, no qual o investigador compara a exactidão de um teste novo com a de um padrão de referência (“*gold standard*”), em grupos com ou sem as condições definidas.

Na apreciação da qualidade do estudo, os aspectos a ter em conta são:

- o espectro da população com conhecimento dos detalhes e proporções de cada um dos grupos, sendo aplicados ambos os testes a todos os participantes;
- ocultação aos investigadores dos resultados obtidos com a realização do primeiro teste para evitar enviesamento dos resultados finais;
- replicabilidade dos resultados dos testes em indivíduos diferentes ou ao mesmo indivíduo em momentos diferentes, assegurando-se que a variável medida é a mesma.

Quando a questão diz respeito a um prognóstico com vista a se encontrar um padrão provável ou o resultado de uma doença ou problema de saúde particular, o estudo de coorte é o mais apropriado com a exposição (ou não) de indivíduos, sem interferência do investigador na sua selecção, a um determinado factor de risco, durante um período de tempo estabelecido.

A apreciação da qualidade do estudo deve ter em consideração:

- a importância da constituição de uma amostra representativa num ponto comum do curso da sua vida / doença (neste caso, preferencialmente no seu início) para que os resultados não sejam influenciados de forma negativa;
- a adequação da duração do estudo à manifestação dos resultados;
- a investigação das razões da perda do seguimento dos participantes do estudo, que serão tidas em consideração na apresentação dos resultados (uma perda inferior a 5% não produz alterações significativas ao contrário de uma perda que rondar 20%);
- a definição dos resultados com antecedência, pois a medição dos resultados subjectivos pode ser uma fonte de enviesamento, ocultando-se, do investigador, as características clínicas e os factores prognósticos do participante, quando se medem resultados objectivos;
- a presença de variáveis inesperadas, nomeadamente, quando os estudos decorrem durante largos períodos de tempo.

Os estudos de coorte são estudos observacionais, também prospectivos, uma vez que o acompanhamento dos participantes se faz ao longo do tempo, desde o momento zero, com o registo dos resultados observados. Quando a aleatorização dos ensaios clínicos é impraticável ou não ética, são os estudos de coorte que podem fornecer a evidência desejada, apresentando como condicionantes o tempo, quando o estudo é longo, e a falta da referida aleatorização, porque a exposição e o tratamento podem confundir-se com outras variáveis.(153)

Perante uma situação rara ou um período de latência considerável, recorre-se aos estudos de casos – controlo cuja essência se centra num determinado desfecho a partir do qual se faz o retrocesso para se encontrar os factores de risco conducentes àquele final; para isso, compara-se um grupo de indivíduos que apresentem um desfecho similar com um grupo de indivíduos que não o apresente, mas com características semelhantes, podendo denotar-se uma maior susceptibilidade ao aparecimento de erros relacionados com a história da exposição.(154)

As séries de casos e os casos clínicos constituem os estudos encontrados na base da hierarquia da evidência, não estando submetidos a controlo e avaliação regulares, o que não significa que não assumam importância na falta de melhor evidência disponível. De salientar que podem ser um ponto de partida para a formulação de questões clínicas.(151,155-162)

A prática da apreciação crítica faz com que, facilmente, se consiga reconhecer a utilidade de determinado artigo, embora se ressalve que as amostras de população a que se recorre na investigação não são exactamente idênticas ao doente em questão, fazendo com que os resultados credíveis obtidos com os artigos considerados, tentem reflectir contextos suficientemente próximos do real.

Assim, a percepção de como as diferenças detectadas podem afectar os resultados, permite apreciar a sua aplicabilidade ao doente, recorrendo-se a um novo conjunto de questões, independentes da questão formulada e do tipo de estudo considerado, as quais têm em conta os seguintes factores:

- clareza na escolha do tipo de estudo;
- descrição adequada das características dos participantes do estudo, com particular referência para aquelas que podem afectar os resultados, como a idade, sexo, comorbilidades, gravidade da doença;
- ponderação na indicação da viabilidade da intervenção ou teste levado a cabo e mencionado no estudo, susceptível de ocasionar mudanças no contexto real da situação;
- avaliação da relação entre os benefícios das alterações a ponderar e os custos associados;
- avaliação da satisfação dos doentes, por meio dos seus valores e preferências, perante a possibilidade de mudança.

O último passo na apreciação clínica da evidência diz respeito à tradução dos resultados obtidos na literatura, em resultados clinicamente relevantes para o doente.

Nesta fase, a afirmação de William Osler “a Medicina é a arte da incerteza e a ciência da probabilidade”(165) permite explicar a dificuldade detectada na interpretação da forma como os resultados da investigação são apresentados, colmatada com a

caracterização e o cálculo de medidas clinicamente significativas para os diferentes tipos de questão e estudo, utilizando-se, para o efeito, tabelas 2x2 como instrumentos de suporte para uma melhor compreensão destas operações.

Na interpretação dos resultados de estudos relativos a uma terapêutica ou intervenção, os participantes são divididos num grupo experimental e num grupo controlo para avaliação do efeito das mesmas, à custa do cálculo do Número Necessário para Tratar (NNT), uma medida que representa o número de doentes que teriam de receber a terapêutica ou intervenção de modo a obter um resultado benéfico num indivíduo extra que, doutra forma, não o teria beneficiado. Quanto menor fôr esse valor, mais importante é o efeito da terapêutica ou intervenção.(139,166,167)

A tabela 7 ajuda na compreensão dos cálculos subjacentes à interpretação dos resultados.

Tabela 7. Interpretação dos resultados de um estudo de avaliação de um efeito de uma terapêutica ou intervenção.(166)

GRUPOS DE ESTUDO	Grupo experimental	EFEITO DA TERAPÊUTICA / INTERVENÇÃO		TOTais
		Presente	Ausente	
	Grupo experimental	a	b	a + b
	Grupo controlo	c	d	c + d
	TOTais	a + c	b + d	a + b + c + d

As células **a** e **b** representam o grupo que recebeu a terapêutica ou intervenção e as células **c** e **d** o grupo que não recebeu. As células **a** e **c** evidenciam a presença do resultado em análise, enquanto as células **b** e **d** evidenciam a sua ausência.

O cálculo do Número Necessário para Tratar exige a determinação de outras medidas intermédias como:

- a Taxa de Ocorrência no grupo experimental (TOE), definida como a percentagem de casos nos quais se denota o efeito da terapêutica ou intervenção recebida,

$$\text{TOE} = (a / (a + b)) \times 100$$

- a Taxa de Ocorrência no grupo controlo (TOC), definida como a percentagem de casos nos quais está presente o efeito desejado, sem terem recebido a terapêutica ou intervenção,

$$\text{TOC} = (c / (c + d)) \times 100$$

A Taxa de Ocorrência no grupo experimental e no grupo controlo representam o Risco Absoluto, ou seja, a percentagem da ocorrência de um evento num determinado grupo de indivíduos.

- a Redução do Risco Absoluto (RRA), o valor necessário para o cálculo do Número Necessário para Tratar, definido como a diferença entre as taxas de ocorrência das duas intervenções,

$$\text{RRA} = \text{TOC} - \text{TOE}$$

obtendo-se o Número Necessário para Tratar através da fórmula matemática,

$$\text{NNT} = 1 / \text{RRA}$$

Na interpretação dos resultados de estudos relativos a um prognóstico ou a uma condição / dano particular em que são comparados, durante um período de tempo estabelecido, os efeitos de um determinado factor num grupo exposto ao mesmo e num grupo não exposto, os resultados correspondem à diferença entre as proporções ou taxas dos ditos efeitos atribuídas aos grupos constituídos. Determina-se, assim, o Risco Relativo (RR) correspondente à diferença relativa na percentagem atribuída em cada grupo; se o seu valor fôr superior a 3, é pouco provável o enviesamento dos resultados. Também pode ser importante o cálculo do Número Necessário para causar Dano (NND) representativo do número necessário de indivíduos expostos a um determinado factor durante um determinado espaço de tempo para causar um dano extra.(139,166,167)

A tabela 8 ajuda na compreensão dos cálculos subjacentes à interpretação dos resultados.

Tabela 8. Interpretação dos resultados de um estudo de prognóstico ou de uma condição / dano particular.(166)

EXPOSIÇÃO AO FACTOR		EFEITOS DECORRENTES		TAXAS
		Presente	Ausente	
	Grupo exposto	a	b	$a / (a + b)$ (taxa no grupo exposto)
	Grupo não exposto	c	d	$c / (c + d)$ (taxa no grupo não exposto)

As células **a** e **b** representam o grupo exposto a um determinado factor e as células **c** e **d** o grupo não exposto. As células **a** e **c** evidenciam a presença dos efeitos decorrentes da exposição, enquanto as células **b** e **d** evidenciam a sua ausência.

O Risco Relativo calcula-se matematicamente, segundo a fórmula,

$$\text{RR} = (a / (a + b)) / (c / (c + d))$$

enquanto que, para o cálculo do Número Necessário para causar Dano, tem de se calcular primariamente, o Aumento do Risco Absoluto (ARA), indicador da dimensão da diferença entre os grupos,

$$\text{ARA} = (a / (a + b)) - (c / (c + d))$$

$$\text{NND} = 1 / \text{ARA}$$

Na interpretação dos resultados de estudos relativos a testes de diagnóstico ou a métodos de apreciação, a realização de medições permite ao profissional avaliar o valor de conjunto de variáveis num ou mais indivíduos e, com isso, elaborar diagnósticos, testar hipóteses, avaliar a dimensão dos problemas de saúde. As duas medidas fundamentais a que se pode recorrer são a sensibilidade e a especificidade.(139,166,167)

A sensibilidade mede a capacidade de detecção de algo que existe; logo, é útil a obtenção de um valor de sensibilidade alta, porque a detecção de um resultado negativo no teste realizado exclui realmente um diagnóstico positivo, havendo uma menor probabilidade de se obterem resultados falsamente negativos.

A especificidade mede a capacidade da não detecção de eventos inexistentes; logo, também é útil a obtenção de um valor de especificidade alta, porque a detecção de um resultado positivo no teste de um doente admite de facto um resultado positivo, havendo uma maior probabilidade da não obtenção de resultados falsamente positivos.

De qualquer forma, apesar da sua utilidade enquanto valores elevados, isso raramente se verifica no mesmo teste, variando ambas as medidas na razão inversa o que, dependendo das circunstâncias, faz recair o interesse sobre uma ou outra.

Para a determinação da sensibilidade e da especificidade, parte-se de um diagnóstico conhecido, sendo dividida a amostra da população representativa num grupo que apresenta a característica de interesse e outro que não apresenta, para uma

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comparação entre um teste em estudo e um teste de referência, também designado de “gold standard”.

A tabela 9 ajuda na compreensão dos cálculos subjacentes à interpretação dos resultados.

Tabela 9. Interpretação dos resultados de um estudo de um teste de diagnóstico ou método de apreciação.(166)

		MÉTODO PADRÃO ("GOLD STANDARD")		TOTais
		Positivo	Negativo	
MÉTODO EM ESTUDO	Positivo	a	b	a + b
	Negativo	c	d	c + d
TOTais		a + c	b + d	a + b + c + d

A célula **a** representa o conjunto de indivíduos que apresentam a característica em análise no teste em estudo e no teste de referência (verdadeiros positivos). A célula **b** representa o conjunto de indivíduos que não apresentam a característica, apesar do resultado positivo no teste em estudo (falsos positivos). A célula **c** representa os indivíduos que apresentam a característica, embora o teste em estudo não o evidencie (falsos negativos). A célula **d** representa os indivíduos que não apresentam a característica em estudo, resultado mostrado de forma negativa por ambos os testes (verdadeiros negativos). Logo, os indivíduos que realmente apresentam a característica em estudo são representados pelas células **a** e **c**, enquanto que os indivíduos incluídos nas células **b** e **d** não a apresentam.

A sensibilidade (S), como medida da proporção de casos resultantes da concordância dos valores positivos do teste em estudo com os resultados totais do teste de referência, calcula-se como a razão percentual entre os verdadeiros positivos e o total de positivos do teste de referência.

$$S = a / (a + c)$$

A especificidade (E), como medida da proporção de casos resultantes da concordância dos valores negativos do teste em estudo com os resultados totais do teste de referência, calcula-se como a razão percentual entre os verdadeiros negativos e o total de negativos do teste de referência.

$$E = d / (b + d)$$

No cálculo de qualquer medida, as variações das amostras utilizadas influenciam os valores finais, convencionando-se o uso dos intervalos de confiança de 95%, a variação em torno de um ponto estimado num estudo em que o resultado verdadeiro se encontra em 95 de 100 ocasiões, para uma estimativa do valor real destes parâmetros. A precisão da estimativa será tanto maior quanto menor for a diferença destes intervalos de confiança.

Relacionados com os conceitos explicitados, mas numa perspectiva de estimativa da presença ou não da doença, surgem novas medidas – o valor preditivo positivo (VPP), ou seja, a probabilidade de um indivíduo apresentar o evento, dado que o resultado do teste empregue foi positivo, e o valor preditivo negativo (VPN), ou seja, a probabilidade de uma pessoa tem de não apresentar o evento, dado que o resultado do teste foi negativo.

Substituindo na tabela anterior o método de referência pela presença da doença e o método em estudo pelo resultado do teste, estas medidas são calculadas, em percentagem, da seguinte forma,

$$\boxed{\mathbf{VPP = a / (a + b)}}$$

$$\boxed{\mathbf{VPN = d / (c + d)}}$$

e variam com a situação da doença num dado momento ou período, ou seja, com a prevalência do evento no grupo estudado. Quanto maior a prevalência da doença, maior será o valor preditivo positivo do teste e menor o valor preditivo negativo; quanto menor a prevalência da doença, menor será o valor preditivo positivo do teste e maior o valor preditivo negativo.

Para refinar a interpretação do profissional acerca da probabilidade da presença ou não de uma doença num determinado indivíduo, recorre-se, a partir dos valores de sensibilidade e especificidade expressos em proporções e não em percentagens, à determinação da Taxa de Probabilidade Positiva (TPP), a proporção entre os resultados verdadeiros positivos e os falsos positivos, e à determinação da Taxa de Probabilidade Negativa, a proporção entre os resultados verdadeiros negativos e os falsos negativos (TPN).

$$\boxed{\mathbf{TPP = sensibilidade / (1 - especificidade)}}$$

$$TPN = (1 - \text{sensibilidade}) / \text{especificidade}$$

Quanto maior o valor da Taxa de Probabilidade Positiva associado a um teste, maior é a sua capacidade de diagnóstico de uma doença, enquanto que um valor baixo da Taxa de Probabilidade Negativa corresponde a um baixo nível de suspeição da doença, num doente que apresente um resultado negativo do teste efectuado.

Partindo de uma probabilidade inicial de uma doença, também designada de probabilidade pré-teste, dependente da prevalência bem como de uma avaliação clínica rigorosa, e conhecendo-se a taxa de probabilidade do teste a aplicar, consegue-se determinar, com a ajuda de artifícios como o nomograma de Fagan, a chamada probabilidade pós-teste, o indicador do aumento ou diminuição das possibilidades do doente apresentar um resultado do teste positivo ou negativo.(166-176)

Aplicação prática da evidência

A tomada da decisão clínica culmina com a aplicação dos conhecimentos adquiridos, transmitidos e aprovados pelo doente em causa, permitindo fazer uma avaliação do seu comportamento no momento e durante todo o seu acompanhamento clínico, com eventual alteração ou introdução de outros dados susceptíveis de originar novas questões e, por consequência, novas decisões.(111-113,134,144) Aspectos como a segurança, a tolerabilidade, a efectividade, o preço e a simplicidade, devem ser tidos em conta na comparação entre intervenções.(139)

Neste processo que se inicia com a formulação da questão focalizada, o passo orientador da busca da melhor evidência para a tomada rigorosa de uma decisão clínica, ajustada ao doente e determinante nas suas vivências e expectativas, a individualidade inerente, aparente, tem necessariamente de se estender a todo o corpo estrutural que integra o sistema de saúde de forma a poder instituir-se uma cultura baseada na evidência. Para isso, têm de sobressair novas percepções, atitudes, motivações, iniciativas, incentivos, recursos, competências, conhecimentos, comportamentos com a disseminação e implementação de estratégias e directrizes, flexíveis, actualizadas e adaptadas ao contexto local, inspiradoras e receptivas ao espírito de mudança evidenciado.(177-179)

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II

Investigação empírica

CAPÍTULO III



***MÉTODOS E
PROCEDIMENTOS***

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A escolha da abordagem, como ponto de partida para o estudo levado a cabo centrado em duas partes principais, recaiu sobre os resultados clínicos negativos da terapêutica anti-retrovírica, uma vez que existem algumas reacções adversas resultantes da administração destes fármacos que caracterizam a vivência do doente com infecção VIH / SIDA; por outro lado, a nossa formação académica, mais familiarizada com a iatrogenia medicamentosa, impunha um conhecimento mais aprofundado desta temática.

Na primeira parte, desenvolvida em Junho de 2007 com a informação disponível até então, identificámos e analisámos a prevalência dos resultados clínicos negativos da terapêutica anti-retrovírica na literatura.

A prevalência das reacções adversas na literatura, um dos indicadores de medição de saúde sobre a situação clínica num dado instante ou período(180), foi apreciada com base nas respectivas recomendações internacionais que sintetizam a informação considerada essencial, desejável e relevante para o doente, fármaco(s) e reacções adversas.(181)

Para isso, identificámos as bases de dados electrónicas passíveis de fornecerem relatos de casos clínicos do objecto de estudo em causa:

- DIRLINE, um directório de organizações de saúde, projectos e fontes de investigação, pertencendo também à United States National Library of Medicine, acessível através do operador Gateway em <http://dirline.nlm.nih.gov>(146);
- Family Physicians Inquiries Network, um projecto de cariz mundial com vista ao desenvolvimento de uma base de dados de questões ligadas aos cuidados primários e respectivas respostas baseadas na evidência, acompanhadas de comentários científicos, acessível em www.fpin.org(120);
- Parkhurst Exchange, uma base de dados semelhante à anterior, existente no Canadá, acessível em www.parkhurstexchange.com(137);
- TRIP Database Plus - Turning Research into Practice Database for Evidence-Based Medicine, uma base de dados especializada em Medicina Baseada na Evidência, acessível em www.tripdatabase.com(140,149);
- MEDLINE, uma base de dados bibliográfica da United States Library of Medicine e National Institutes of Health, acessível gratuitamente através do operador PubMed em www.ncbi.nlm.nih.gov/entrez/query.fcgi.(120,140,146,182,183)

A informação pretendida foi localizada com a combinação das palavras-chave “AIDS”, “adverse effects” e “case reports” com o operador booleano AND.

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A pesquisa bibliográfica reporta-se exclusivamente à MEDLINE, através da PubMed, com a construção de determinadas equações segundo uma estratégia de pesquisa genérica desenvolvida para a busca de informação relativa a iatrogenia medicamentosa, estruturada segundo as características da base de dados, como se esquematiza na figura 6.

Várias abordagens devem ser utilizadas para localizar informação em situações de iatrogenia medicamentosa

Exemplo: Utilizar o MeSH, *subheadings* e limites quando disponível

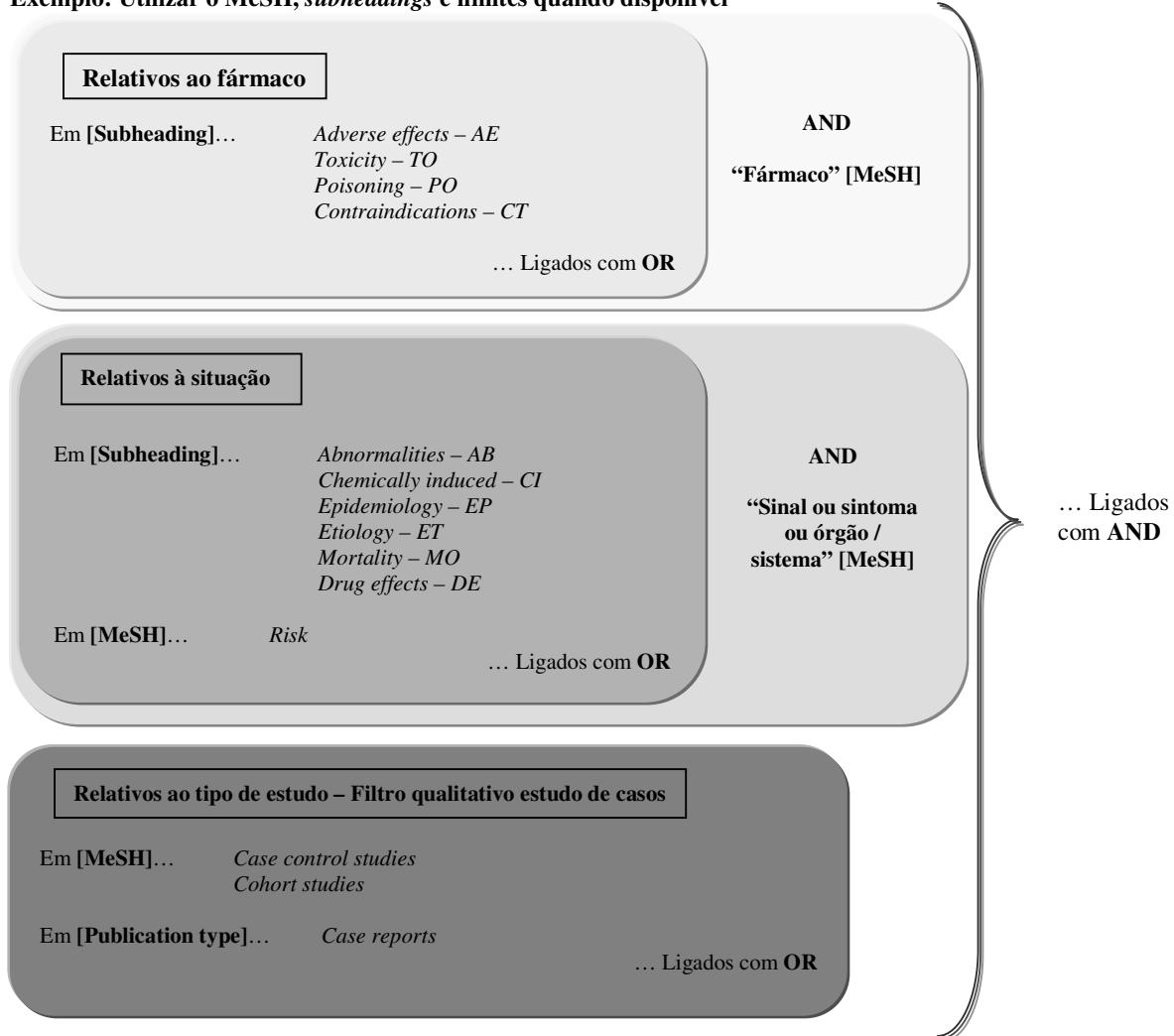


Figura 6. Estratégia de pesquisa desenvolvida para a busca de informação relativa a iatrogenia medicamentosa.(142)

Na construção das equações de pesquisa, recorremos a um vocabulário especial disponível na MEDLINE / PubMed, mais trabalhado e refinado, utilizado na indexação de artigos relevantes, e designado por *Medical Subject Headings* (MeSH).

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Desse modo, procedemos à escolha dos termos e / ou expressões relativos às três principais classes farmacológicas de medicamentos anti-retrovíricos comercializados – inibidores da protease, inibidores da transcriptase reversa e inibidores da entrada, concretamente, inibidores da fusão.

A definição original destes termos, encontrada no MeSH, é apresentada na tabela 10.

Tabela 10. Termos MeSH relativos às classes farmacológicas de medicamentos anti-retrovíricos e respectivas definições.

Termo MeSH	Definição
<i>HIV Protease Inhibitors</i>	<i>Inhibitors of HIV PROTEASE, an enzyme required for production of proteins needed for viral assembly.</i> <i>Year introduced: 1993</i>
<i>Reverse Transcriptase Inhibitors</i>	<i>Inhibitors of reverse transcriptase (RNA-DIRECTED DNA POLYMERASE), an enzyme that synthesizes DNA on an RNA template.</i> <i>Year introduced: 1996</i>
<i>HIV Fusion Inhibitors</i>	<i>Inhibitors of the fusion of HIV to host cells, preventing viral entry. This includes compounds that block attachment of HIV ENVELOPE PROTEIN GPI20 to CD4 RECEPTORS.</i> <i>Year introduced: 2002</i>

Para além disso, são disponibilizados os chamados “*subheadings*”, ou seja, um conjunto de termos e /ou expressões – qualificadores, ainda mais específicos na identificação dos artigos considerados importantes em determinada área, que se relacionam com as situações clínica e farmacológica e outros assuntos.

Os “*subheadings*” utilizados no trabalho em curso são apresentados na tabela 11 bem como as respectivas definições originais, encontradas no MeSH.

Tabela 11. “Subheadings” utilizados no trabalho em curso e respectivas definições.

Termo Subheading	Definição
<i>Adverse effects</i>	<i>Used with drugs, chemicals, or biological agents in accepted dosage - or with physical agents or manufactured products in normal usage - when intended for diagnostic, therapeutic, prophylactic, or anesthetic purposes. It is used also for adverse effects or complications of diagnostic, therapeutic, prophylactic, anesthetic, surgical, or other procedures, but excludes contraindications for which "contraindications" is used.</i>
<i>Toxicity</i>	<i>Used with drugs and chemicals for experimental human and animal studies of their ill effects. It includes studies to determine the margin of safety or the reactions accompanying administration at various dose levels. It is used also for exposure to environmental agents. Poisoning should be considered for life-threatening exposure to environmental agents.</i>
<i>Poisoning</i>	<i>Used with drugs, chemicals, and industrial materials for human or animal poisoning, acute or chronic, whether the poisoning is accidental, occupational, suicidal, by medication error, or by environmental exposure.</i>
<i>Contraindications</i>	<i>Used with drugs, chemicals, and biological and physical agents in any disease or physical state that might render their use improper, undesirable, or inadvisable. Used also with contraindicated diagnostic, therapeutic, prophylactic, anesthetic, surgical or other procedures.</i>
<i>Abnormalities</i>	<i>Used with organs for congenital defects producing changes in the morphology of the organ. It is used also for abnormalities in animals.</i>
<i>Chemically induced</i>	<i>Used for biological phenomena, diseases, syndromes, congenital abnormalities, or symptoms caused by endogenous or exogenous substances.</i>
<i>Drug effects</i>	<i>Used with organs, regions, tissues, or organisms and physiological and psychological processes for the effects of drugs and chemicals.</i>

Assim, seleccionámos os “subheadings” relativos a reacções adversas - “*adverse effects*”, “*toxicity*”, “*poisoning*”, “*contraindications*”.

Escolhemos também filtros metodológicos qualitativos, recorrendo a outros qualificadores disponíveis quer no MeSH quer na PubMed, em geral, relativos ao tipo de estudo, neste caso, estudo de casos clínicos - “*case reports*”, “*case-control studies*”, “*cohort studies*”, tal como mostra a Figura 6.

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A construção da equação de pesquisa resulta, finalmente, da combinação, com o recurso aos operadores booleanos AND e OR, da combinação dos termos e/ou expressões relativos à classe farmacológica, dos “*subheadings*” relativos a reacções adversas, dos filtros qualitativos e, ainda, de um limite ou “*subset*”, disponível na PubMed, o qual impõe a pesquisa de artigos relativos à infecção VIH / SIDA.

Os dados obtidos foram, posteriormente, tratados no sentido de se analisar quais as reacções adversas que surgem mais frequentemente descritas.

Na segunda parte, desenvolvida entre Julho e Agosto de 2008 com a informação disponível na MEDLINE / PubMed até Dezembro de 2007, optimizámos a metodologia de pesquisa com apreciação da sua validade com base na relação entre os instrumentos sensibilidade e especificidade.

Tendo em conta alguns dos passos já descritos, procedemos à construção de novas equações de pesquisa, em três fases escalonadas num nível crescente de complexidade, para posterior comparação dos resultados.

Na primeira fase, construímos equações de pesquisa, associando, com os operadores booleanos AND e OR, os termos e / ou expressões do MeSH relativos às três classes farmacológicas, em separado e em conjunto, e os “*subheadings*” relativos às reacções adversas, utilizados anteriormente.

Os dados relativos a cada equação de pesquisa obtida, foram importados para o programa informático “*Endnote*”, promotor de uma maior facilidade de organização das referências bibliográficas em “*libraries*” com exclusão dos artigos duplicados.

Mediante a respectiva análise do título e do corpo do resumo ou “*abstract*”, também através do referido programa informático, os artigos foram divididos em dois grupos:

- um grupo de artigos directamente relacionados com reacções adversas que designámos como padrão de ouro ou “*gold standard*”;
- um grupo de artigos não relacionados directamente com reacções adversas, abordando assuntos como interacções medicamentosas, infecções oportunistas, profilaxia pós-exposição, opiniões científicas,

para, seguidamente, se calcular, em percentagem, os valores da sensibilidade e especificidade para cada uma das equações de pesquisa. Para tal, o cálculo matemático que tivemos em conta sofreu a devida adaptação ao conceito inerente a estes instrumentos de medida.

Assim sendo, a tabela 12 descreve a aplicação dos passos descritos, com base nas estratégias de pesquisa construídas,

Tabela 12. Aplicação do método descrito, com base nas estratégias de pesquisa construídas, para o cálculo percentual da sensibilidade e especificidade.

Resultados da estratégia de pesquisa	“Gold standard”		NÃO
	SIM	SIM	
	a	b	
NÃO	c	d	

a = artigos obtidos na estratégia de pesquisa coincidentes com o grupo “gold standard”

b = artigos obtidos na estratégia de pesquisa não coincidentes com o grupo “gold standard”

c = artigos pertencentes ao grupo “gold standard” não obtidos na estratégia de pesquisa

d = artigos não pertencentes ao grupo “gold standard” e não obtidos na estratégia de pesquisa

a+b = número de artigos obtidos para cada estratégia de pesquisa

a+c = número de artigos que se incluem no grupo “gold standard”

determinando-se os parâmetros mencionados com as seguintes fórmulas matemáticas,

$$\boxed{\text{Sensibilidade} = a / (a+c)}$$

$$\boxed{\text{Especificidade} = d / (b+d)}$$

Nesta primeira fase, ainda recolhemos as palavras-chave relativas à situação clínica, indexadas em MeSH, que aparecem referenciadas mais frequentemente no grupo “gold standard” correspondente a cada estratégia de pesquisa, para posterior tratamento. Estes dados foram exportados do programa “Endnote” para o programa “Microsoft Excel 97/2003/XP”.

Na segunda fase, construímos outras equações de pesquisa, que incluem, para além dos termos e / ou expressões relativos à classe farmacológica e dos “subheadings” relativos a reacções adversas, o filtro qualitativo relativo ao tipo de estudo – estudo de casos, revisões sistemáticas e ensaios clínicos aleatorizados, recorrendo aos correspondentes qualificadores disponíveis em MeSH e na PubMed, em geral (estudo de casos - “case reports”, “case-control studies”, “cohort studies”; revisões sistemáticas - “review literature”, “review”, “meta-analysis”, “systematic”; ensaios clínicos aleatorizados - “clinical trials”, “random allocation”, “product surveillance, postmarketing”, “randomized controlled trial”).

Capítulo III

A figura 7 complementa a informação relativa ao filtro qualitativo utilizado, mostrada na figura 6.

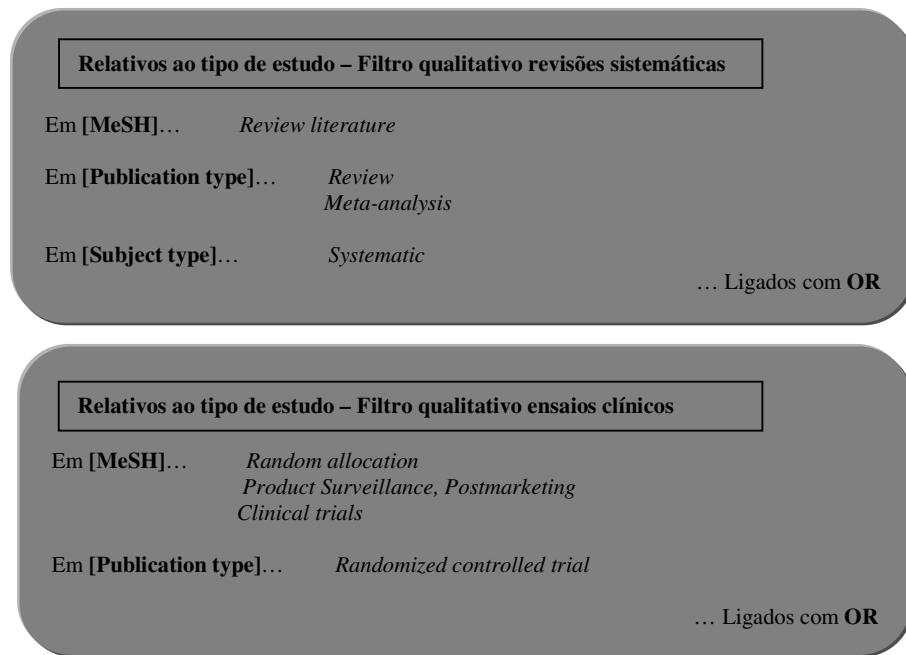


Figura 7. Filtros qualitativos relativos aos tipos de estudo ensaios clínicos aleatorizados e revisões sistemáticas.(142)

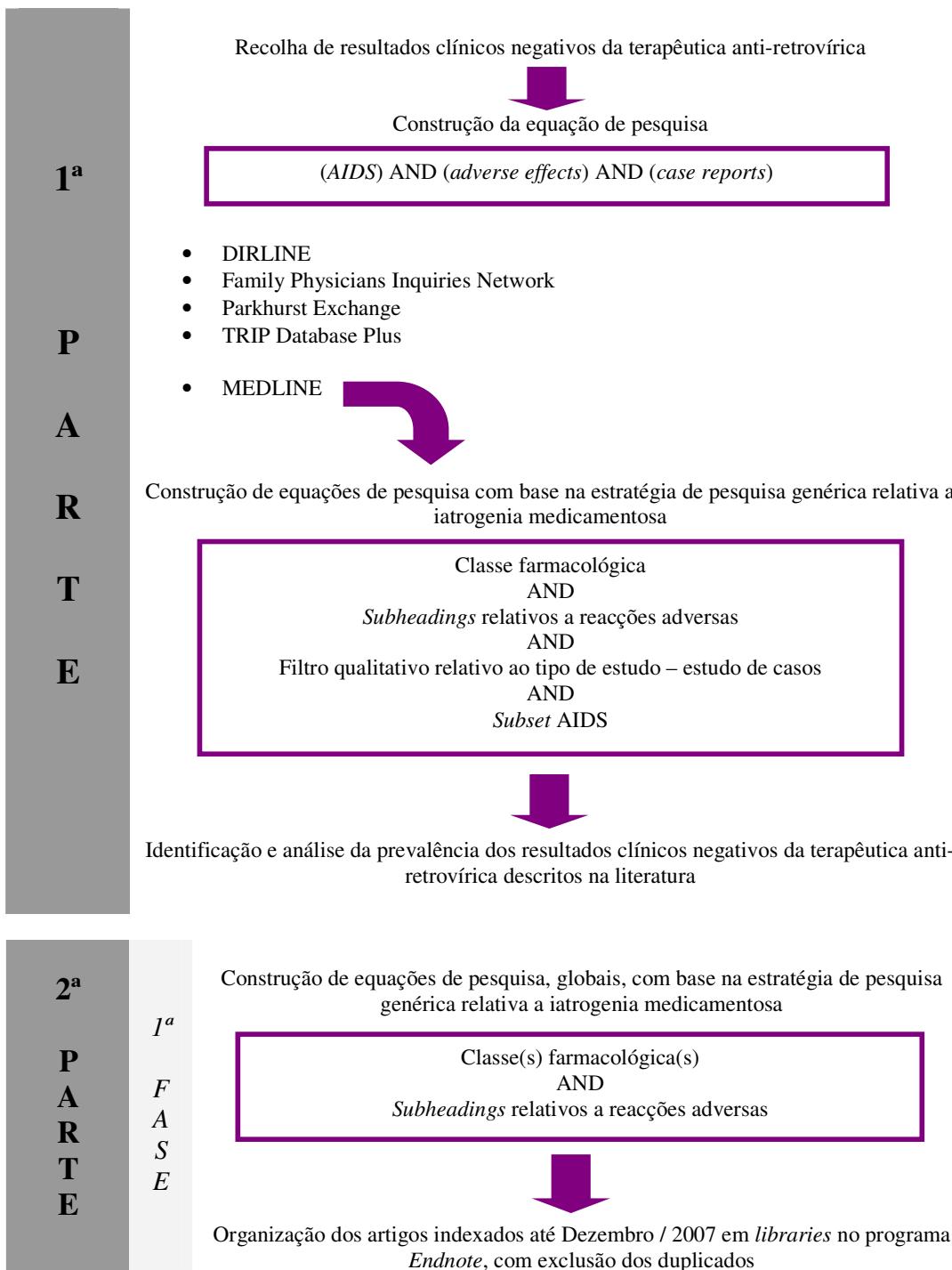
Os passos referentes ao recurso ao programa informático “*Endnote*”, a divisão dos artigos nos dois grupos citados e o cálculo percentual da sensibilidade e da especificidade para cada uma destas equações de pesquisa, foram repetidos.

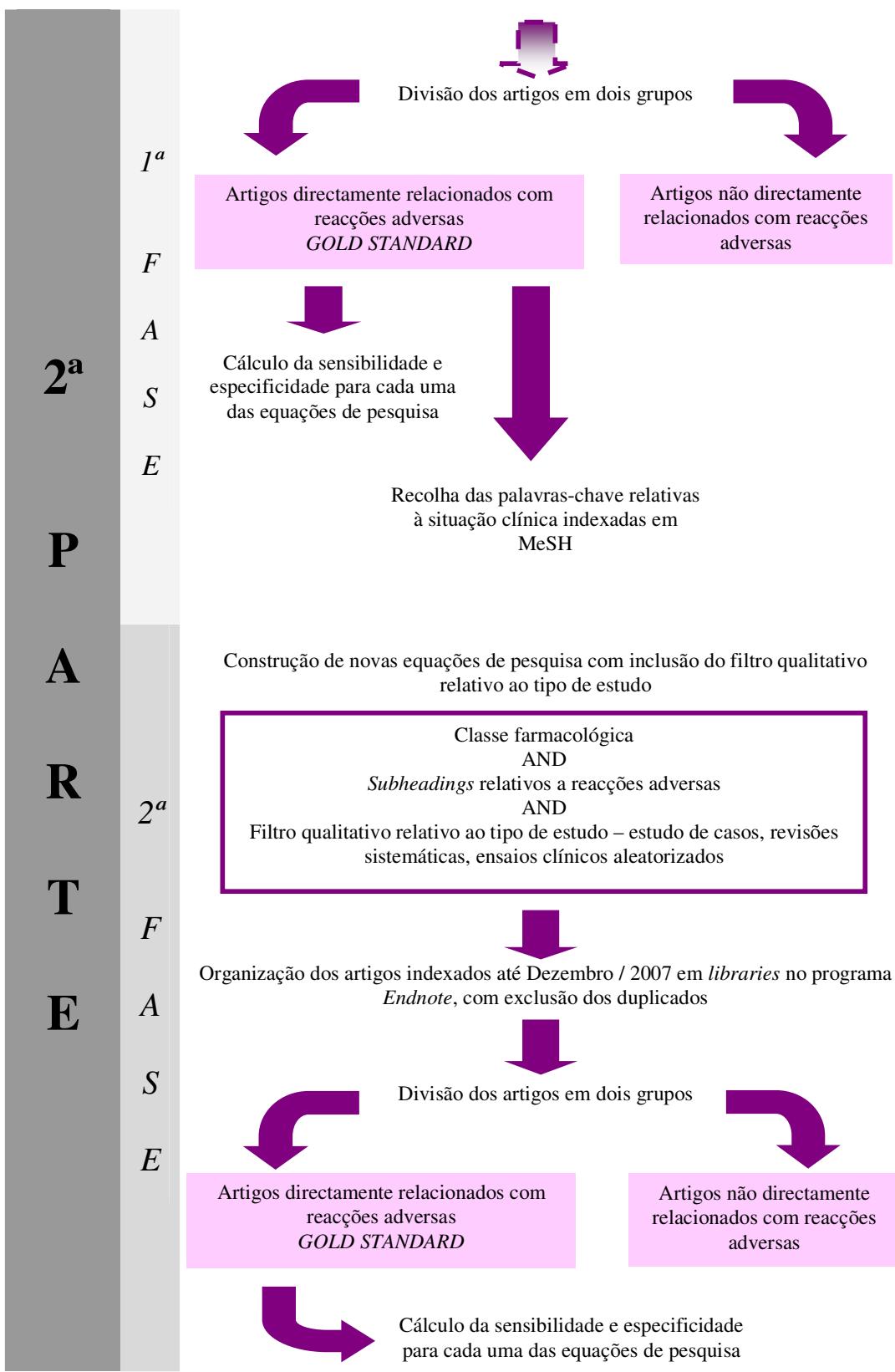
Na terceira fase, construímos novas equações de pesquisa, adicionando aos termos e / ou expressões relativos à classe farmacológica, aos “*subheadings*” relativos a reacções adversas e ao filtro qualitativo relativo ao tipo de estudo, as palavras-chave relativas à situação clínica indexadas em MeSH, recolhidas na primeira fase, e novos “*subheadings*” relacionados com a situação clínica propriamente dita, disponíveis também em MeSH - “*abnormalities*”, “*chemically induced*”, “*drug effects*”.

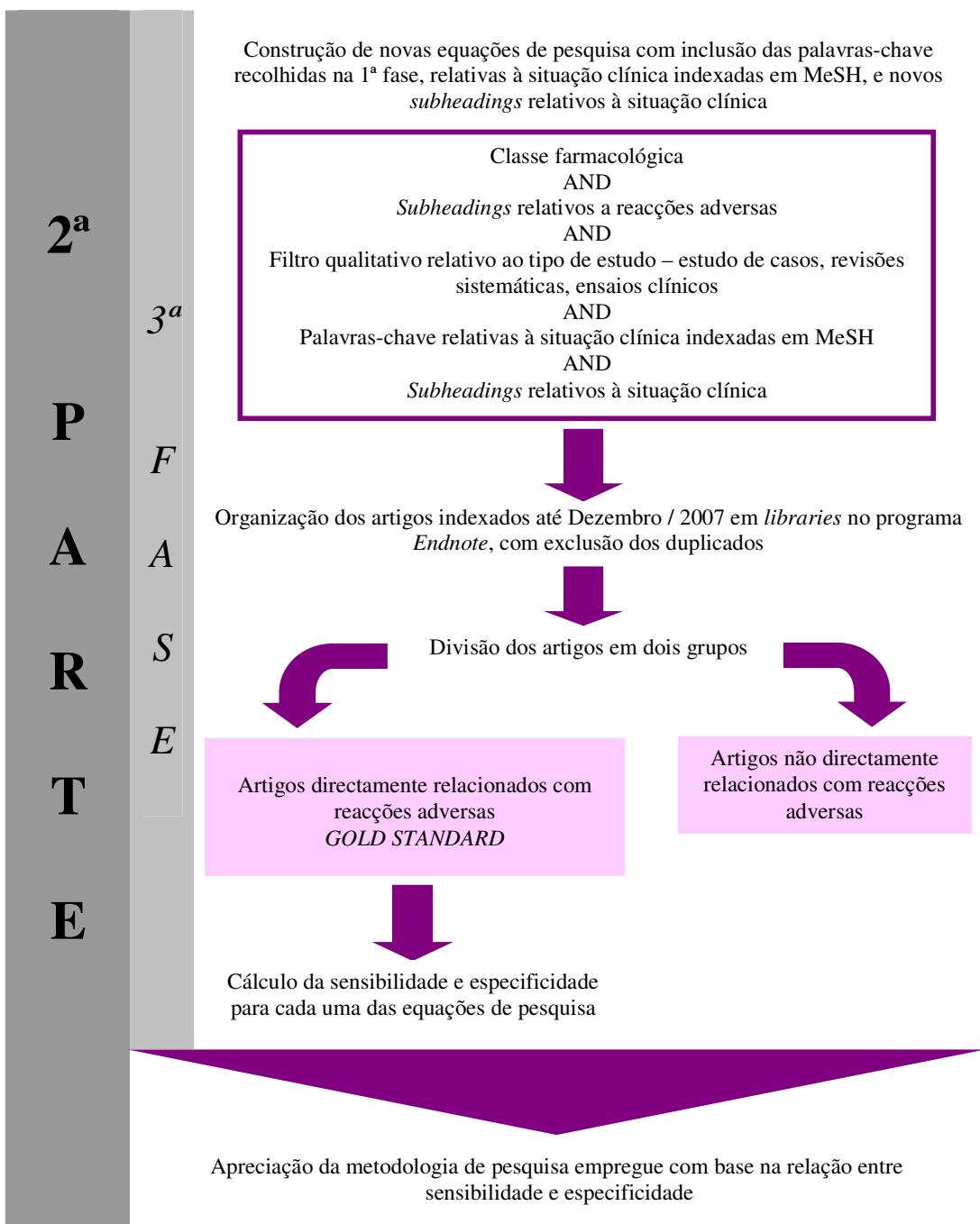
Mais uma vez, os procedimentos finais englobaram o recurso ao programa informático “*Endnote*”, a diferenciação dos artigos nos dois grupos analisados, sendo, ainda, calculados os valores da sensibilidade e especificidade para cada destas equações.

Capítulo III

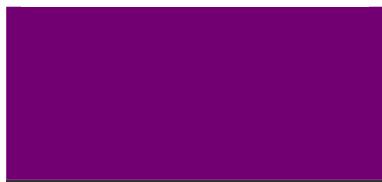
O fluxograma elaborado, apresentado em seguida, simplifica com clareza a descrição do método efectuada.







CAPÍTULO IV



RESULTADOS

Capítulo IV

O fluxograma elaborado simplifica com clareza os resultados obtidos com o trabalho desenvolvido.

1^a PARTE (Junho de 2007)

Recolha de resultados clínicos negativos da terapêutica anti-retrovírica apenas na MEDLINE

Construção de equações de pesquisa com base na estratégia de pesquisa genérica relativa a iatrogenia medicamentosa – p. 91

Equação 1.

294 artigos

Equação 2.

242 artigos

Equação 3.

11 artigos

547 artigos

170 artigos em texto integral

Identificação e análise da prevalência dos resultados clínicos negativos da terapêutica anti-retrovírica descritos na literatura

2^a PARTE (Julho / Agosto de 2008)

I^a Construção de equações de pesquisa, globais, com base na estratégia de pesquisa genérica relativa a iatrogenia medicamentosa (artigos indexados até Dezembro / 2007) – p. 93

F

Equação 1.1.

1852 artigos

Equação 1.2.

1315 artigos

Equação 1.3.

85 artigos

Equação global

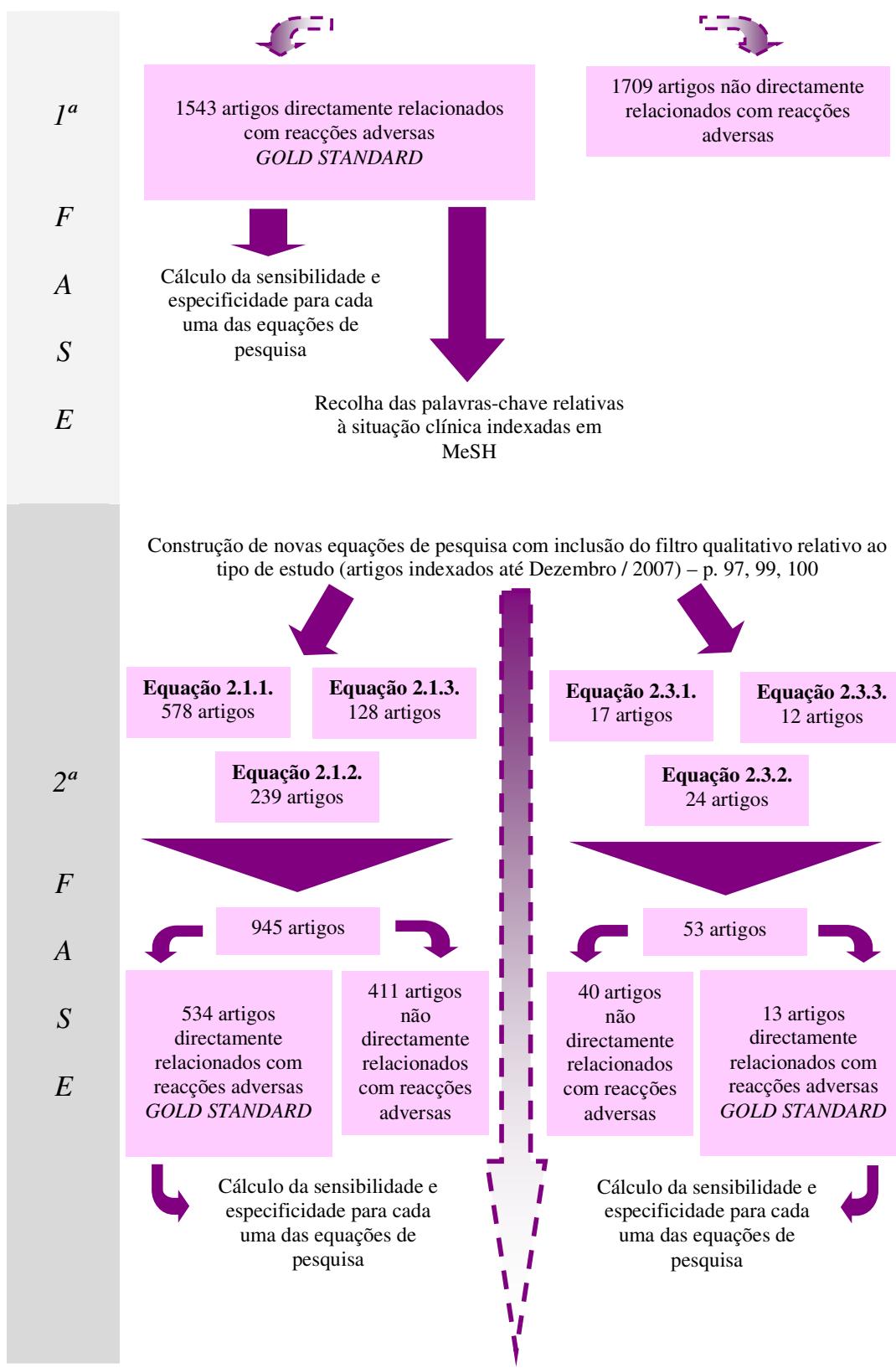
0 artigos

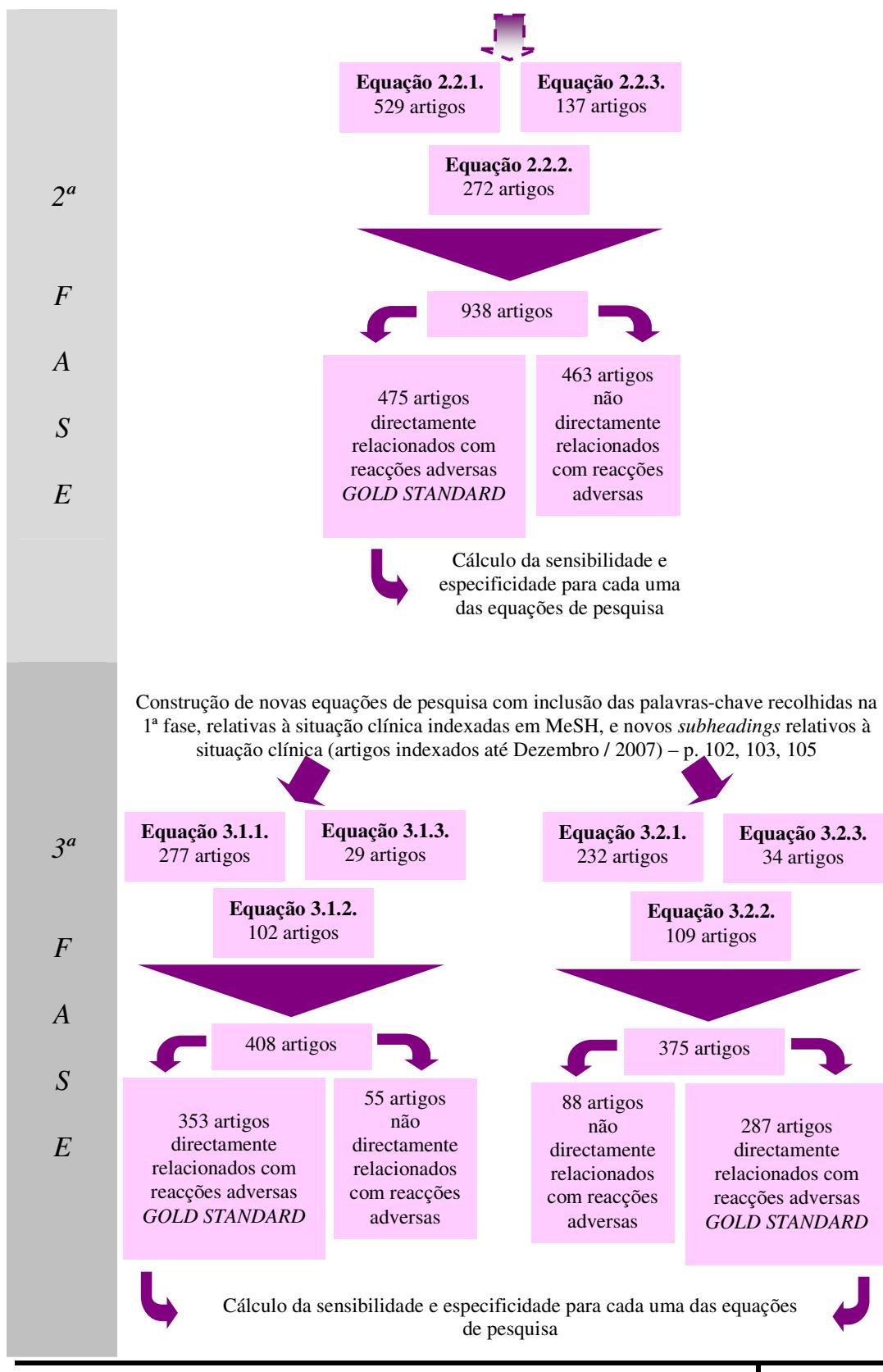
A

S

E

3252 artigos





Capítulo IV

Na primeira parte do trabalho, realizada em Junho de 2007, após a identificação das bases de dados passíveis de fornecerem relatos de casos clínicos com a combinação de palavras descrita

(AIDS) AND (adverse effects) AND (case reports)

apenas se obtiveram resultados na base de dados MEDLINE, através do operador PubMed.

As equações construídas com base na estratégia de pesquisa genérica desenvolvida para a busca de informação relativa a iatrogenia medicamentosa são apresentadas em seguida.

1. (“HIV protease inhibitors” [MeSH]) AND (“Adverse effects” [Subheading] OR “Toxicity” [Subheading] OR “Poisoning” [Subheading] OR “Contraindications” [Subheading]) AND (“case reports” [Publication Type] OR “case control studies” [MeSH] OR “cohort studies” [MeSH]) AND AIDS[Subset]

O número de artigos obtido foi de 294 artigos.

2. (“Reverse transcriptase inhibitors” [MeSH]) AND (“Adverse effects” [Subheading] OR “Toxicity” [Subheading] OR “Poisoning” [Subheading] OR “Contraindications” [Subheading]) AND (“case reports” [Publication Type] OR “case control studies” [MeSH] OR “cohort studies” [MeSH]) AND AIDS[Subset]

O número de artigos obtido foi de 242 artigos.

3. (“HIV fusion inhibitors” [MeSH]) AND (“Adverse effects” [Subheading] OR “Toxicity” [Subheading] OR “Poisoning” [Subheading] OR “Contraindications” [Subheading]) AND (“case reports” [Publication Type] OR “case control studies” [MeSH] OR “cohort studies” [MeSH]) AND AIDS[Subset]

O número de artigos obtido foi de 11 artigos.

Com estas equações, obtivemos um total de 547 artigos, sendo o acesso em texto integral possível em apenas 170 artigos.

Analizando o conteúdo dos 170 documentos, sintetizámos, na tabela 13, as reacções adversas das classes farmacológicas de medicamentos anti-retrovíricos mais frequentemente descritas.

Tabela 13. Reacções adversas relativas à terapêutica anti-retrovírica mais frequentemente descritas na MEDLINE / PubMed.

Efeitos adversos	Informações a salientar
Grupo farmacológico	
INIBIDORES ENTRADA (INIBIDORES FUSÃO)	Reacções de hipersensibilidade cutâneas Hepatotoxicidade
INIBIDORES TRANSCRIPTASE REVERSA ANÁLOGOS DE NUCLEÓSIDOS	Sintomas maníacos Reacções de hipersensibilidade Hiperlactatémia / acidose láctica Miopatia Lipodistrofia Ototoxicidade Mielotoxicidade
INIBIDORES TRANSCRIPTASE REVERSA NÃO ANÁLOGOS DE NUCLEÓSIDOS	Lipodistrofia Ginecomastia Sintomas maníacos Complicações hematopoiéticas Hiperlactatémia Reacções cutâneas (rash, DRESS, síndrome Stevens-Johnson)
INIBIDORES TRANSCRIPTASE REVERSA ANÁLOGOS DE NUCLEÓTIDOS	Nefrotoxicidade Osteomalácia Acidose láctica
INIBIDORES PROTEASE	Patologias reumatológicas Hiperpigmentação do cabelo, unhas e pele e outras reacções cutâneas Hiperlipidémia Lipodistrofia Hipertensão e outras alterações cardíacas Atrofia renal, nefropatia tubulointersticial, urolitíase Diabetes <i>Mellitus</i> Alterações hematológicas

Na segunda parte do trabalho, realizada em Julho e Agosto de 2008, a optimização da metodologia de pesquisa avaliada com base na relação entre os instrumentos sensibilidade e especificidade atravessou três fases para comparação dos resultados, considerando-se, para o efeito, somente os artigos indexados na MEDLINE / PubMed até Dezembro de 2007.

Na primeira fase, construímos novas equações de pesquisa, com as quais obtivemos, no total, 3252 artigos.

Capítulo IV

1.1. ("HIV Protease Inhibitors"[MeSH]) AND ("Adverse effects"[Subheading] OR "Toxicity"[Subheading] OR "Poisoning"[Subheading] OR "Contraindications"[Subheading])

O número total de artigos obtido foi de 1852 artigos.

1.2. ("Reverse transcriptase Inhibitors"[MeSH]) AND ("Adverse effects"[Subheading] OR "Toxicity"[Subheading] OR "Poisoning"[Subheading] OR "Contraindications"[Subheading])

O número total de artigos obtido foi de 1315 artigos, com exclusão dos artigos duplicados.

1.3. ("HIV fusion Inhibitors"[MeSH]) AND ("Adverse effects[Subheading] OR "Toxicity[Subheading] OR "Poisoning"[Subheading] OR "Contraindications"[Subheading])

O número total de artigos obtido foi de 85 artigos, com exclusão dos artigos duplicados.

Conjugando as três equações,

("HIV protease inhibitors"[MeSH] OR "Reverse transcriptase inhibitors"[MeSH] OR "HIV fusion Inhibitors"[MeSH]) AND ("Adverse effects"[Subheading] OR "Toxicity"[Subheading] OR "Poisoning"[Subheading] OR "Contraindications"[Subheading])

os artigos obtidos são todos duplicados dos anteriores o que nos levou a trabalhar somente com as equações de pesquisa em que os termos e / ou expressões correspondentes à classe farmacológica de medicamentos anti-retrovíricos aparecem em separado.

Dividindo os 3252 artigos, obtidos com as primeiras três equações de pesquisa, nos dois grupos descritos metodologicamente, obtivemos:

- 1543 artigos directamente relacionados com reacções adversas – grupo “*gold standard*”;
- 1709 artigos não directamente relacionados com reacções adversas.

Prosseguindo com o cálculo percentual da sensibilidade e especificidade, para cada uma das estratégias de pesquisa, os resultados obtidos foram os expostos nas tabelas seguintes.

Capítulo IV

Tabela 14. Valores percentuais de sensibilidade e especificidade para a estratégia de pesquisa 1.1..

		INIBIDORES DA PROTEASE “Gold standard”		
Resultados da estratégia de pesquisa 1.1.	SIM	SIM	NÃO	a+b = 1852
	NÃO	931	921	
Sensibilidade = 60,3% Especificidade = 46,1%				

Tabela 15. Valores percentuais de sensibilidade e especificidade para a estratégia de pesquisa 1.2..

		INIBIDORES DA TRANSCRIPTASE REVERSA “Gold standard”		
Resultados da estratégia de pesquisa 1.2.	SIM	SIM	NÃO	a+b = 1315
	NÃO	953	984	
Sensibilidade = 38,2% Especificidade = 57,6%				

Tabela 16. Valores percentuais de sensibilidade e especificidade para a estratégia de pesquisa 1.3..

		INIBIDORES DA FUSÃO “Gold standard”		
Resultados da estratégia de pesquisa 1.3.	SIM	SIM	NÃO	a+b = 85
	NÃO	1521	1646	
Sensibilidade = 1,4% Especificidade = 96,3%				

A recolha das palavras-chave relativas à situação clínica, indexadas em MeSH, é apresentada, nas tabelas seguintes, por ordem decrescente até a uma frequência de aparecimento superior ou igual a 10 vezes, para cada uma das estratégias de pesquisa,

com exceção das palavras-chave referentes às estratégias de pesquisa que incluem os inibidores da fusão por se apresentarem como as únicas relativas à situação clínica.

Tabela 17. Palavras-chave relativas à situação clínica e respectiva frequência de aparecimento – estratégia de pesquisa 1.1..

INIBIDORES DA PROTEASE	
Palavras – chave relativas à situação clínica	Frequência
Lipodystrophy	146
Hyperlipidemias	115
Triglycerides	81
Insulin resistance	79
Cholesterol	70
Adipose tissue	69
HIV-associated lipodystrophy syndrome	59
Body composition	51
Lipids	50
Cardiovascular diseases	42
Diabetes Mellitus	38
Blood glucose	35
Insulin	35
Kidney calculi	34
Hypertriglyceridemia	31
Liver	28
Crystallization	27
Hypercholesterolemia	24
Kidney failure, acute	24
Lipid metabolism	22
Cholesterol, HDL	21
Hyperglycemia	21
Kidney diseases	21
Myocardial infarction	21
Coronary disease	20
Adipocytes	19
Kidney	17
Mitochondria	16
Body mass index	15
Glucose	15
Cholesterol, LDL	14
Urinary calculi	14
Diarrhea	13
Dyslipidemias	13
Metabolic syndrome X	13
Creatinine	12
Lipoproteins	12
Pancreatitis	12
Ureteral calculi	12
Drug eruptions	11
Hemorrhage	11
Hepatitis, toxic	11
Metabolic diseases	11
Nephritis, interstitial	11
Alopecia	10
Body weight	10
Endothelium, vascular	10
Liver diseases	10

Capítulo IV

Tabela 18. Palavras-chave relativas à situação clínica e respectiva frequência de aparecimento – estratégia de pesquisa 1.2..

INIBIDORES DA TRANSCRIPTASE REVERSA	
Palavras – chave relativas à situação clínica	Frequência
Acidosis, lactic	90
Mitochondria	74
DNA, mitochondrial	70
Lipodystrophy	59
Drug hypersensitivity	44
Lactic acid	44
HIV-associated lipodystrophy syndrome	37
Liver	37
Liver diseases	27
Mitochondrial diseases	23
Peripheral Nervous System diseases	22
Adipose tissue	21
Exanthema	20
Body composition	18
Drug eruptions	17
Mitochondria, liver	17
Hepatitis, toxic	16
Lipids	14
Alanine transaminase	12
Fatty liver	12
Kidney diseases	12
Fanconi syndrome	11
Insulin resistance	11
Lactates	11
Creatinine	10
Muscle, skeletal	10

Tabela 19. Palavras-chave relativas à situação clínica e respectiva frequência de aparecimento – estratégia de pesquisa 1.3..

INIBIDORES DA FUSÃO	
Palavras – chave relativas à situação clínica	Frequência
Desensitization, immunologic	4
Drug eruptions	4
Drug hypersensitivity	3

Na segunda fase, as equações de pesquisa construídas incluem os itens referidos nas equações anteriores acrescidos da nova fracção correspondente ao filtro qualitativo relativo ao tipo de estudo, propositadamente salientada – estudo de casos, revisões sistemáticas e ensaios clínicos aleatorizados, respectivamente.

Para os inibidores da protease, obtivemos um total de 945 artigos, com as seguintes equações de pesquisa.

2.1.1. ("HIV Protease Inhibitors"[MeSH]) AND ("Adverse effects"[Subheading] OR "Toxicity"[Subheading] OR "Poisoning"[Subheading] OR "Contraindications"[Subheading]) AND ("case reports"[Publication type] OR "case-control studies"[MeSH] OR "cohort studies"[MeSH])

O número total de artigos obtido foi de 578 artigos.

2.1.2. ("HIV Protease Inhibitors"[MeSH]) AND ("Adverse effects"[Subheading] OR "Toxicity"[Subheading] OR "Poisoning"[Subheading] OR "Contraindications"[Subheading]) AND ("review literature"[MeSH] OR "review"[Publication type] OR "meta-analysis"[Publication type] OR "systematic"[Subject Type])

O número total de artigos obtido foi de 239 artigos, com exclusão dos artigos duplicados.

2.1.3. ("HIV Protease Inhibitors"[MeSH]) AND ("Adverse effects"[Subheading] OR "Toxicity"[Subheading] OR "Poisoning"[Subheading] OR "Contraindications"[Subheading]) AND ("clinical trials"[MeSH] OR "random allocation"[MeSH] OR "product surveillance, postmarketing"[MeSH] OR "randomized controlled trial"[Publication Type])

O número total de artigos obtido foi de 128 artigos, com exclusão dos artigos duplicados.

Dividindo os 945 artigos, obtidos com as três equações de pesquisa respeitantes aos inibidores da protease, nos dois grupos descritos metodologicamente, obtivemos:

- 534 artigos directamente relacionados com reacções adversas – grupo “*gold standard*”;
- 411 artigos não directamente relacionados com reacções adversas.

Prosseguindo com o cálculo percentual da sensibilidade e especificidade, para cada uma das estratégias de pesquisa, os resultados obtidos foram os expostos nas tabelas seguintes.

Capítulo IV

Tabela 20. Valores percentuais de sensibilidade e especificidade para a estratégia de pesquisa 2.1.1..

		INIBIDORES DA PROTEASE (tipo de estudo: estudo de casos)		<i>“Gold standard”</i>
Resultados da estratégia de pesquisa 2.1.1.	SIM	SIM	NÃO	
	NÃO	141	226	
				a+b = 578

Sensibilidade = 73,6%
Especificidade = 55,0%

Tabela 21. Valores percentuais de sensibilidade e especificidade para a estratégia de pesquisa 2.1.2..

		INIBIDORES DA PROTEASE (tipo de estudo: revisões sistemáticas)		<i>“Gold standard”</i>
Resultados da estratégia de pesquisa 2.1.2.	SIM	SIM	NÃO	
	NÃO	419	287	
				a+b = 239

Sensibilidade = 21,5%
Especificidade = 69,8%

Tabela 22. Valores percentuais de sensibilidade e especificidade para a estratégia de pesquisa 2.1.3..

		INIBIDORES DA PROTEASE (tipo de estudo: ensaios clínicos)		<i>“Gold standard”</i>
Resultados da estratégia de pesquisa 2.1.3.	SIM	SIM	NÃO	
	NÃO	508	309	
				a+b = 128

Sensibilidade = 4,9%
Especificidade = 75,2%

Para os inibidores da transcriptase reversa, obtivemos um total de 938 artigos, com as seguintes equações de pesquisa.

Capítulo IV

2.2.1. ("Reverse Transcriptase Inhibitors"[MeSH]) AND ("Adverse effects"[Subheading] OR "Toxicity"[Subheading] OR "Poisoning"[Subheading] OR "Contraindications"[Subheading]) **AND** ("case reports"[Publication Type] **OR** "case-control studies"[MeSH] **OR** "cohort studies"[MeSH])

O número total de artigos obtido foi de 529 artigos.

2.2.2. ("Reverse Transcriptase Inhibitors"[MeSH]) AND ("Adverse effects"[Subheading] OR "Toxicity"[Subheading] OR "Poisoning"[Subheading] OR "Contraindications"[Subheading]) **AND** ("review literature"[MeSH] **OR** "review"[Publication Type] **OR** "meta-analysis"[Publication Type] **OR** "systematic"[Subject Type])

O número total de artigos obtido foi de 272 artigos, com exclusão dos artigos duplicados.

2.2.3. ("Reverse Transcriptase Inhibitors"[MeSH]) AND ("Adverse effects"[Subheading] OR "Toxicity"[Subheading] OR "Poisoning"[Subheading] OR "Contraindications"[Subheading]) **AND** ("clinical trials"[MeSH] **OR** "random allocation"[MeSH] **OR** "product surveillance, postmarketing"[MeSH] **OR** "randomized controlled trial"[Publication Type])

O número total de artigos obtido foi de 137 artigos, com exclusão dos artigos duplicados.

Dividindo os 938 artigos, obtidos com as três equações de pesquisa respeitantes aos inibidores da transcriptase reversa, nos dois grupos descritos metodologicamente, obtivemos:

- 475 artigos directamente relacionados com reacções adversas – grupo “*gold standard*”;
- 463 artigos não directamente relacionados com reacções adversas.

Prosseguindo com o cálculo percentual da sensibilidade e especificidade, para cada uma das estratégias de pesquisa, os resultados obtidos foram os expostos nas tabelas seguintes.

Tabela 23. Valores percentuais de sensibilidade e especificidade para a estratégia de pesquisa 2.2.1..

INIBIDORES DA TRANSCRIPTASE REVERSA (tipo de estudo: estudo de casos)		“ <i>Gold standard</i> ”		$a+b = 529$
Resultados da estratégia de pesquisa 2.2.1.	SIM	SIM	NÃO	
SIM	320	209		
NÃO	155	254		
Sensibilidade = 67,4% Especificidade = 54,9%				

Capítulo IV

Tabela 24. Valores percentuais de sensibilidade e especificidade para a estratégia de pesquisa 2.2.2..

		INIBIDORES DA TRANSCRIPTASE REVERSA (tipo de estudo: revisões sistemáticas)		<i>"Gold standard"</i>
		SIM	NÃO	
Resultados da estratégia de pesquisa 2.2.2.	SIM	120	152	a+b = 272
	NÃO	355	311	
Sensibilidade = 25,3% Especificidade = 67,2%				

Tabela 25. Valores percentuais de sensibilidade e especificidade para a estratégia de pesquisa 2.2.3..

		INIBIDORES DA TRANSCRIPTASE REVERSA (tipo de estudo: ensaios clínicos)		<i>"Gold standard"</i>
		SIM	NÃO	
Resultados da estratégia de pesquisa 2.2.3.	SIM	35	102	a+b = 137
	NÃO	440	361	
Sensibilidade = 7,4% Especificidade = 78,0%				

Para os inibidores da fusão, obtivemos um total de 53 artigos, com as seguintes equações de pesquisa.

2.3.1. ("HIV Fusion Inhibitors"[MeSH]) AND ("Adverse effects"[Subheading] OR "Toxicity"[Subheading] OR "Poisoning"[Subheading] OR "Contraindications"[Subheading]) AND ("case reports"[Publication Type] OR "case-control studies"[MeSH] OR "cohort studies"[MeSH])

O número total de artigos obtido foi de 17 artigos.

2.3.2. ("HIV Fusion Inhibitors"[MeSH]) AND ("Adverse effects"[Subheading] OR "Toxicity"[Subheading] OR "Poisoning"[Subheading] OR "Contraindications[Subheading]) AND ("review literature"[MeSH] OR "review"[Publication Type] OR "meta-analysis"[Publication Type] OR "systematic"[Subject Type])

O número total de artigos obtido foi de 24 artigos, sem detecção de artigos duplicados.

2.3.3. ("HIV Fusion Inhibitors"[MeSH]) AND ("Adverse effects"[Subheading] OR "Toxicity"[Subheading] OR "Poisoning"[Subheading] OR "Contraindications"[Subheading]) AND

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("clinical trials"[MeSH] OR "random allocation"[MeSH] OR "product surveillance, postmarketing"[MeSH] OR "randomized controlled trial"[Publication type])

O número total de artigos obtido foi de 12 artigos, com exclusão dos artigos duplicados.

Dividindo os 53 artigos, obtidos com as três equações de pesquisa respeitantes aos inibidores da fusão, nos dois grupos descritos metodologicamente, obtivemos:

- 13 artigos directamente relacionados com reacções adversas – grupo “*gold standard*”;
- 40 artigos não directamente relacionados com reacções adversas.

Prosseguindo com o cálculo percentual da sensibilidade e especificidade, para cada uma das estratégias de pesquisa, os resultados obtidos foram os expostos nas tabelas seguintes.

Tabela 26. Valores percentuais de sensibilidade e especificidade para a estratégia de pesquisa 2.3.1..

		INIBIDORES DA FUSÃO (tipo de estudo: estudo de casos)		<i>“Gold standard”</i>	$a+b = 17$
Resultados da estratégia de pesquisa 2.3.1.	SIM	SIM	NÃO		
	NÃO	3	33		

Sensibilidade = 77,0%
Especificidade = 82,5%

Tabela 27. Valores percentuais de sensibilidade e especificidade para a estratégia de pesquisa 2.3.2..

		INIBIDORES DA FUSÃO (tipo de estudo: revisões sistemáticas)		<i>“Gold standard”</i>	$a+b = 24$
Resultados da estratégia de pesquisa 2.3.2.	SIM	SIM	NÃO		
	NÃO	11	18		

Sensibilidade = 15,4%
Especificidade = 45,0%

Tabela 28. Valores percentuais de sensibilidade e especificidade para a estratégia de pesquisa 2.3.3..

		INIBIDORES DA FUSÃO (tipo de estudo: ensaios clínicos)		<i>"Gold standard"</i>
Resultados da estratégia de pesquisa 2.3.3.	SIM	SIM	NÃO	
	NÃO	12	29	
			Sensibilidade = 7,7% Especificidade = 72,5%	

Na terceira fase, a máxima complexidade na construção das equações de pesquisa é alcançada com a adição, às equações anteriores, dos dados relativos à situação clínica, ou seja, as palavras-chave relativas à situação clínica mais frequentes, indexadas em MeSH e recolhidas na primeira fase da segunda parte do trabalho e de novos “*subheadings*” relacionados também com a situação clínica, propositadamente salientados.

Com as palavras-chave relativas à situação clínica associadas aos inibidores da protease, obtivemos um total de 408 artigos, com as seguintes equações de pesquisa.

3.1.1. ((“lipodystrophy”[MeSH] OR “hyperlipidemias”[MeSH] OR “triglycerides”[MeSH] OR “insulin resistance”[MeSH] OR “cholesterol”[MeSH] OR “adipose tissue”[MeSH] OR “HIV-associated lipodystrophy syndrome”[MeSH] OR “body composition”[MeSH] OR “lipids”[MeSH] OR “cardiovascular diseases”[MeSH] OR “Diabetes Mellitus”[MeSH] OR “blood glucose”[MeSH] OR “insulin”[MeSH] OR “kidney calculi”[MeSH] OR “hypertriglyceridemia”[MeSH] OR “liver”[MeSH] OR “crystallization”[MeSH] OR “hypercholesterolemia”[MeSH] OR “kidney failure, acute”[MeSH] OR “lipid metabolism”[MeSH] OR “cholesterol, HDL”[MeSH] OR “hyperglycemia”[MeSH] OR “kidney diseases”[MeSH] OR “myocardial infarction”[MeSH] OR “coronary disease”[MeSH] OR “adipocytes”[MeSH] OR “kidney”[MeSH] OR “mitochondria”[MeSH] OR “body mass index”[MeSH] OR “glucose”[MeSH] OR “cholesterol, LDL”[MeSH] OR “urinary calculi”[MeSH] OR “diarrhea”[MeSH] OR “dyslipidemias”[MeSH] OR “metabolic syndrome X”[MeSH] OR “creatinine”[MeSH] OR “lipoproteins”[MeSH] OR “pancreatitis”[MeSH] OR “ureteral calculi”[MeSH] OR “drug eruptions”[MeSH] OR “hemorrhage”[MeSH] OR “hepatitis, toxic”[MeSH] OR “metabolic diseases”[MeSH] OR “nephritis, interstitial”[MeSH] OR “alopecia”[MeSH] OR “body weight”[MeSH] OR “endothelium, vascular”[MeSH] OR “liver diseases”[MeSH]) AND (“abnormalities”[Subheading] OR “chemically induced”[Subheading] OR “drug effects”[Subheading])) AND ((“HIV protease inhibitors”[MeSH]) AND (“Adverse effects”[Subheading] OR “Toxicity”[Subheading] OR “Poisoning”[Subheading] OR “Contraindications”[Subheading])) AND (“case reports”[Publication Type] OR “case-control studies”[MeSH] OR “cohort studies”[MeSH]))

O número total de artigos obtido foi de 277 artigos.

3.1.2. ((“lipodystrophy”[MeSH] OR “hyperlipidemias”[MeSH] OR “triglycerides”[MeSH] OR “insulin resistance”[MeSH] OR “cholesterol”[MeSH] OR “adipose tissue”[MeSH] OR “HIV-associated lipodystrophy syndrome”[MeSH] OR “body composition”[MeSH] OR “lipids”[MeSH]

OR "cardiovascular diseases"[MeSH] OR "Diabetes Mellitus"[MeSH] OR "blood glucose"[MeSH] OR "insulin"[MeSH] OR "kidney calculi"[MeSH] OR "hypertriglyceridemia"[MeSH] OR "liver"[MeSH] OR "crystallization"[MeSH] OR "hypercholesterolemia"[MeSH] OR "kidney failure, acute"[MeSH] OR "lipid metabolism"[MeSH] OR "cholesterol, HDL"[MeSH] OR "hyperglycemia"[MeSH] OR "kidney diseases"[MeSH] OR "myocardial infarction"[MeSH] OR "coronary disease"[MeSH] OR "adipocytes"[MeSH] OR "kidney"[MeSH] OR "mitochondria"[MeSH] OR "body mass index"[MeSH] OR "glucose"[MeSH] OR "cholesterol, LDL"[MeSH] OR "urinary calculi"[MeSH] OR "diarrhea"[MeSH] OR "dyslipidemias"[MeSH] OR "metabolic syndrome X"[MeSH] OR "creatinine"[MeSH] OR "lipoproteins"[MeSH] OR "pancreatitis"[MeSH] OR "ureteral calculi"[MeSH] OR "drug eruptions"[MeSH] OR "hemorrhage"[MeSH] OR "hepatitis, toxic"[MeSH] OR "metabolic diseases"[MeSH] OR "nephritis, interstitial"[MeSH] OR "alopecia"[MeSH] OR "body weight"[MeSH] OR "endothelium, vascular"[MeSH] OR "liver diseases"[MeSH] AND ("abnormalities"[Subheading] OR "chemically induced"[Subheading] OR "drug effects"[Subheading])) AND ((HIV protease inhibitors"[MeSH]) AND ("Adverse effects"[Subheading] OR "Toxicity"[Subheading] OR "Poisoning"[Subheading] OR "Contraindications"[Subheading])) AND ("review literature"[MeSH] OR "review"[Publication Type] OR "meta-analysis"[Publication Type] OR "systematic"[Subject Type])

O número total de artigos obtido foi de 102 artigos, com exclusão dos artigos duplicados.

3.1.3. ((*"lipodystrophy"*[MeSH] OR "hyperlipidemias"[MeSH] OR "triglycerides"[MeSH] OR "insulin resistance"[MeSH] OR "cholesterol"[MeSH] OR "adipose tissue"[MeSH] OR "HIV-associated lipodystrophy syndrome"[MeSH] OR "body composition"[MeSH] OR "lipids"[MeSH] OR "cardiovascular diseases"[MeSH] OR "Diabetes Mellitus"[MeSH] OR "blood glucose"[MeSH] OR "insulin"[MeSH] OR "kidney calculi"[MeSH] OR "hypertriglyceridemia"[MeSH] OR "liver"[MeSH] OR "crystallization"[MeSH] OR "hypercholesterolemia"[MeSH] OR "kidney failure, acute"[MeSH] OR "lipid metabolism"[MeSH] OR "cholesterol, HDL"[MeSH] OR "hyperglycemia"[MeSH] OR "kidney diseases"[MeSH] OR "myocardial infarction"[MeSH] OR "coronary disease"[MeSH] OR "adipocytes"[MeSH] OR "kidney"[MeSH] OR "mitochondria"[MeSH] OR "body mass index"[MeSH] OR "glucose"[MeSH] OR "cholesterol, LDL"[MeSH] OR "urinary calculi"[MeSH] OR "diarrhea"[MeSH] OR "dyslipidemias"[MeSH] OR "metabolic syndrome X"[MeSH] OR "creatinine"[MeSH] OR "lipoproteins"[MeSH] OR "pancreatitis"[MeSH] OR "ureteral calculi"[MeSH] OR "drug eruptions"[MeSH] OR "hemorrhage"[MeSH] OR "hepatitis, toxic"[MeSH] OR "metabolic diseases"[MeSH] OR "nephritis, interstitial"[MeSH] OR "alopecia"[MeSH] OR "body weight"[MeSH] OR "endothelium, vascular"[MeSH] OR "liver diseases"[MeSH] AND ("abnormalities"[Subheading] OR "chemically induced"[Subheading] OR "drug effects"[Subheading])) AND ((HIV protease inhibitors"[MeSH]) AND ("Adverse effects"[Subheading] OR "Toxicity"[Subheading] OR "Poisoning"[Subheading] OR "Contraindications"[Subheading])) AND ("clinical trials"[MeSH] OR "random allocation"[MeSH] OR "product surveillance, postmarketing"[MeSH] OR "randomized controlled trial"[Publication Type])

O número total de artigos obtido foi de 29 artigos, com exclusão dos artigos duplicados.

Dividindo os 408 artigos, obtidos com as três equações de pesquisa respeitantes aos inibidores da fusão, nos dois grupos descritos metodologicamente, obtivemos:

- 353 artigos directamente relacionados com reacções adversas – grupo "*gold standard*";
 - 55 artigos não directamente relacionados com reacções adversas.
-

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Prosseguindo com o cálculo percentual da sensibilidade e especificidade, para cada uma das estratégias de pesquisa, os resultados obtidos foram os expostos nas tabelas seguintes.

Tabela 29. Valores percentuais de sensibilidade e especificidade para a estratégia de pesquisa 3.1.1..

INIBIDORES DA PROTEASE (palavras-chave relativas à situação clínica)		<i>“Gold standard”</i>		
Resultados da estratégia de pesquisa 3.1.1.	SIM	SIM	NÃO	
	SIM	247	30	a+b = 277
	NÃO	106	25	
Sensibilidade = 70,0% Especificidade = 45,4%				

Tabela 30. Valores percentuais de sensibilidade e especificidade para a estratégia de pesquisa 3.1.2..

INIBIDORES DA PROTEASE (palavras-chave relativas à situação clínica)		<i>“Gold standard”</i>		
Resultados da estratégia de pesquisa 3.1.2.	SIM	SIM	NÃO	
	SIM	86	16	a+b = 102
	NÃO	267	39	
Sensibilidade = 24,4% Especificidade = 71,0%				

Tabela 31. Valores percentuais de sensibilidade e especificidade para a estratégia de pesquisa 3.1.3..

INIBIDORES DA PROTEASE (palavras-chave relativas à situação clínica)		<i>“Gold standard”</i>		
Resultados da estratégia de pesquisa 3.1.3.	SIM	SIM	NÃO	
	SIM	20	9	a+b = 29
	NÃO	333	46	
Sensibilidade = 5,7% Especificidade = 83,6%				

Com as palavras-chave relativas à situação clínica associadas aos inibidores da transcriptase reversa, obtivemos um total de 375 artigos, com as seguintes equações de pesquisa.

3.2.1. ((acidosis, lactic"[MeSH] OR "mitochondria"[MeSH] OR "DNA, mitochondrial"[MeSH] OR "lipodystrophy"[MeSH] OR "drug hypersensitivity"[MeSH] OR "lactic acid"[MeSH] OR "HIV-associated lipodystrophy syndrome"[MeSH] OR "liver"[MeSH] OR "liver diseases"[MeSH] OR "mitochondrial diseases"[MeSH] OR "peripheral nervous system diseases"[MeSH] OR "adipose tissue"[MeSH] OR "exanthema"[MeSH] OR "body composition"[MeSH] OR "drug eruptions"[MeSH] OR "mitochondria, liver"[MeSH] OR "hepatitis, toxic"[MeSH] OR "lipids"[MeSH] OR "alanine, transaminase"[MeSH] OR "fatty liver"[MeSH] OR "kidney diseases"[MeSH] OR "fanconi syndrome"[MeSH] OR "insulin resistance"[MeSH] OR "lactates"[MeSH] OR creatinine[MeSH] OR "muscle, skeletal"[MeSH]) AND ("abnormalities"[Subheading] OR "chemically induced"[Subheading] OR "drug effects"[Subheading])) AND ((Reverse Transcriptase Inhibitors"[MeSH])) AND ((Adverse effects"[Subheading] OR "Toxicity"[Subheading] OR "Poisoning"[Subheading] OR "Contraindications"[Subheading])) AND ("case reports"[Publication Type] OR "case-control studies"[MeSH] OR "cohort studies"[MeSH])

O número total de artigos obtido foi de 232 artigos.

3.2.2. ((acidosis, lactic"[MeSH] OR "mitochondria"[MeSH] OR "DNA, mitochondrial"[MeSH] OR "lipodystrophy"[MeSH] OR "drug hypersensitivity"[MeSH] OR "lactic acid"[MeSH] OR "HIV-associated lipodystrophy syndrome"[MeSH] OR "liver"[MeSH] OR "liver diseases"[MeSH] OR "mitochondrial diseases"[MeSH] OR "peripheral nervous system diseases"[MeSH] OR "adipose tissue"[MeSH] OR "exanthema"[MeSH] OR "body composition"[MeSH] OR "drug eruptions"[MeSH] OR "mitochondria, liver"[MeSH] OR "hepatitis, toxic"[MeSH] OR "lipids"[MeSH] OR "alanine, transaminase"[MeSH] OR "fatty liver"[MeSH] OR "kidney diseases"[MeSH] OR "fanconi syndrome"[MeSH] OR "insulin resistance"[MeSH] OR "lactates"[MeSH] OR "creatinine"[MeSH] OR "muscle, skeletal"[MeSH]) AND ("abnormalities"[Subheading] OR "chemically induced"[Subheading] OR "drug effects"[Subheading])) AND ((Reverse Transcriptase Inhibitors"[MeSH])) AND ((Adverse effects"[Subheading] OR "Toxicity"[Subheading] OR "Poisoning"[Subheading] OR "Contraindications"[Subheading])) AND ("review literature"[MeSH] OR "review"[Publication Type] OR "meta-analysis"[Publication Type] OR "systematic"[Subject Type])

O número total de artigos obtido foi de 109 artigos, com exclusão dos artigos duplicados.

3.2.3. ((acidosis, lactic"[MeSH] OR "mitochondria"[MeSH] OR "DNA, mitochondrial"[MeSH] OR "lipodystrophy"[MeSH] OR "drug hypersensitivity"[MeSH] OR "lactic acid"[MeSH] OR "HIV-associated lipodystrophy syndrome"[MeSH] OR "liver"[MeSH] OR "liver diseases"[MeSH] OR "mitochondrial diseases"[MeSH] OR "peripheral nervous system diseases"[MeSH] OR "adipose tissue"[MeSH] OR "exanthema"[MeSH] OR "body composition"[MeSH] OR "drug eruptions"[MeSH] OR "mitochondria, liver"[MeSH] OR "hepatitis, toxic"[MeSH] OR "lipids"[MeSH] OR "alanine, transaminase"[MeSH] OR "fatty liver"[MeSH] OR "kidney diseases"[MeSH] OR "fanconi syndrome"[MeSH] OR "insulin resistance"[MeSH] OR "lactates"[MeSH] OR "creatinine"[MeSH] OR "muscle, skeletal"[MeSH]) AND ("abnormalities"[Subheading] OR "chemically induced"[Subheading] OR "drug effects"[Subheading])) AND ((Reverse Transcriptase Inhibitors"[MeSH])) AND ((Adverse effects"[Subheading] OR "Toxicity"[Subheading] OR "Poisoning"[Subheading] OR "Contraindications"[Subheading])) AND ("clinical trials"[MeSH] OR "random allocation"[MeSH] OR "product surveillance, postmarketing"[MeSH] OR "randomized controlled trial"[Publication Type])

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O número total de artigos obtido foi de 34 artigos, com exclusão dos artigos duplicados.

Dividindo os 375 artigos, obtidos com as três equações de pesquisa respeitantes aos inibidores da transcriptase reversa, nos dois grupos descritos metodologicamente, obtivemos:

- 287 artigos directamente relacionados com reacções adversas – grupo “*gold standard*”;
- 88 artigos não directamente relacionados com reacções adversas.

Prosseguindo com o cálculo percentual da sensibilidade e especificidade, para cada uma das estratégias de pesquisa, os resultados obtidos foram os expostos nas tabelas seguintes.

Tabela 32. Valores percentuais de sensibilidade e especificidade para a estratégia de pesquisa 3.2.1..

		“Gold standard”			
Resultados da estratégia de pesquisa 3.2.1.	SIM	SIM	NÃO	a+b = 232	
	NÃO	112	31		
Sensibilidade = 61,0%					
Especificidade = 35,2%					

Tabela 33. Valores percentuais de sensibilidade e especificidade para a estratégia de pesquisa 3.2.2..

		“Gold standard”			
Resultados da estratégia de pesquisa 3.2.2.	SIM	SIM	NÃO	a+b = 109	
	NÃO	200	66		
Sensibilidade = 30,3%					
Especificidade = 75,0%					

Tabela 34. Valores percentuais de sensibilidade e especificidade para a estratégia de pesquisa 3.2.3..

		INIBIDORES DA TRANSCRIPTASE REVERSA (palavras-chave relativas à situação clínica)		
		“Gold standard”		
Resultados da estratégia de pesquisa 3.2.3.	SIM	SIM	NÃO	$a+b = 34$
	NÃO	262	79	
Sensibilidade = 8,7% Especificidade = 89,9%				

Com as palavras-chave relativas à situação clínica associadas aos inibidores da fusão, obtivemos um único artigo, com as seguintes equações de pesquisa, tornando impraticáveis os procedimentos habituais subsequentes.

3.3.1. ((“Desensitization, immunologic”[MeSH] OR “drug eruptions”[MeSH] OR “drug hypersensitivity”[MeSH]) AND (“abnormalities”[Subheading] OR “chemically induced”[Subheading] OR “drug effects”[Subheading])) AND ((“HIV fusion Inhibitors”[MeSH] AND (“Adverse effects”[Subheading] OR “Toxicity”[Subheading] OR “Poisoning”[Subheading] OR “Contraindications”[Subheading])) AND (“case reports”[Publication Type] OR “case-control studies”[MeSH] OR “cohort studies”[MeSH]))

3.3.2. ((“Desensitization, immunologic”[MeSH] OR “drug eruptions”[MeSH] OR “drug hypersensitivity”[MeSH]) AND (“abnormalities”[Subheading] OR “chemically induced”[Subheading] OR “drug effects”[Subheading])) AND ((“HIV fusion Inhibitors”[MeSH] AND (“Adverse effects”[Subheading] OR “Toxicity”[Subheading] OR “Poisoning”[Subheading] OR “Contraindications”[Subheading])) AND (“review literature”[MeSH] OR “review”[Publication Type] OR “meta-analysis”[Publication Type] OR “systematic”[Subject Type]))

3.3.3. ((“Desensitization, immunologic”[MeSH] OR “drug eruptions”[MeSH] OR “drug hypersensitivity”[MeSH]) AND (“abnormalities”[Subheading] OR “chemically induced”[Subheading] OR “drug effects”[Subheading])) AND ((“HIV fusion Inhibitors”[MeSH] AND (“Adverse effects”[Subheading] OR “toxicity”[Subheading] OR “Poisoning”[Subheading] OR “Contraindications”[Subheading])) AND (“clinical trials”[MeSH] OR “random allocation”[MeSH] OR “product surveillance, postmarketing”[MeSH] OR “randomized controlled trial”[Publication Type]))

O único artigo disponível com estas equações foi obtido com a equação 3.3.2..

Para efeitos de comparação dos valores da sensibilidade e especificidade obtidos com as diferentes equações de pesquisa para as três classes farmacológicas, sintetizámos os resultados na tabela seguinte.

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Tabela 35. Comparação dos valores de sensibilidade e especificidade obtidos com as diferentes equações de pesquisa para as classes farmacológicas.

	1 ^a Fase	2 ^a Fase			3 ^a Fase		
		Casos	Revisões	Ens. Clínicos	Sit. + Casos	Sit. + Revisões	Sit. + Ens. Clínicos
Inibidores da protease	S = 60,3 E = 46,1	S = 73,6 E = 55,0	S = 21,5 E = 69,8	S = 4,9 E = 75,2	S = 70,0 E = 45,4	S = 24,4 E = 71,0	S = 5,7 E = 83,6
Inibidores da transcriptase reversa	S = 38,2 E = 57,6	S = 67,4 E = 54,9	S = 25,3 E = 67,2	S = 7,4 E = 78,0	S = 61,0 E = 35,2	S = 30,3 E = 75,0	S = 8,7 E = 89,9
Inibidores da fusão	S = 1,4 E = 96,3	S = 77,0 E = 82,5	S = 15,4 E = 45,0	S = 7,7 E = 72,5	Valores não calculados devido a um único artigo obtido		

S = sensibilidade (em percentagem)
E = especificidade (em percentagem)
Casos, Revisões, Ens. Clínicos = filtro qualitativo correspondente aos três tipos de estudo (estudo de casos, revisões sistemáticas, ensaios clínicos aleatorizados)
Sit. = palavras-chave mais frequentes relativas à situação clínica, indexadas em MeSH



***DISCUSSÃO DOS
RESULTADOS***

O desenvolvimento deste trabalho iniciou-se com a necessidade de inclusão de informação clínica relativa a reacções adversas na literatura científica, constatada nos estudos realizados por Blenkinsopp e colaboradores, Loke et colaboradores e Hopewell e colaboradores(184-186), nos quais se realça o papel crucial do doente como detentor deste tipo de informação para que, em caso de suspeição, a reacção adversa seja de imediato comunicada à equipa de profissionais de saúde que o acompanha para se proceder à sua confirmação.

Para facilitar o processo, Kelly e colaboradores(181) esboçaram um conjunto de directrizes para publicação de relatos de casos clínicos na área da segurança, que orientam a recolha dos dados considerados essenciais, desejáveis e relevantes para o doente, para o(s) fármaco(s) e para o(s) efeito(s) adverso(s).

Na primeira parte do trabalho, identificámos e analisámos a prevalência dos resultados clínicos negativos da terapêutica anti-retrovírica descritos em casos clínicos na literatura.

As reacções adversas identificadas correspondem às reacções adversas características dos fármacos anti-retrovíricos. Contudo, corroborando as conclusões dos estudos referidos, a amostra de artigos obtidos é pouco significativa, acentuando-se com a dificuldade no acesso ao seu texto integral. Por outro lado, atendendo à insuficiente clarificação da classificação ATC em relação aos fármacos inibidores da entrada pela sua recente descoberta, apenas foi encontrada a informação pretendida para os fármacos inibidores da fusão.

Loke e colaboradores(187) sugerem, ainda, no seguimento de uma avaliação efectividade *versus* segurança e tolerabilidade de uma intervenção, a referenciar em cada publicação, estratégias para a pesquisa de resultados clínicos negativos. Estas englobam combinações de termos MeSH e “*subheadings*” e palavras recolhidas no título e resumo do artigo, para além de termos relativos ao tipo de estudo, com a pretensão do aumento dos valores da sensibilidade e especificidade.

Na segunda parte do trabalho, pretendemos optimizar uma metodologia de pesquisa dos resultados clínicos negativos da terapêutica anti-retrovírica com a respectiva apreciação baseada nos valores da sensibilidade e especificidade calculados.

Seguindo o método aplicado por Rama(142) na área da segurança em Teratologia que permitiu a obtenção dos resultados previstos, construímos equações de pesquisa, com base numa estratégia de pesquisa genérica para a busca de informação relativa a iatrogenia medicamentosa. A construção das equações de pesquisa decorreu em três fases, num nível crescente de complexidade, com a introdução e combinação de termos MeSH correspondentes às classes de fármacos anti-retrovíricos, “*subheadings*” relativos a reacções adversas, filtros qualitativos relativos ao tipo de estudo (estudo de casos, revisões sistemáticas e ensaios clínicos aleatorizados), palavras-chave relativas à situação clínica indexadas em MeSH e “*subheadings*” relativos à situação clínica.

Tal como na primeira parte, a pesquisa bibliográfica cingiu-se à MEDLINE, através do operador PubMed, visto tratar-se de uma base de dados bibliográfica de acesso gratuito.

As classes farmacológicas de fármacos anti-retrovíricos que compuseram as equações de pesquisa construídas, englobaram os inibidores da protease, os inibidores da transcriptase reversa e os inibidores da fusão, uma vez que não foram encontrados resultados relativos aos novos fármacos inibidores da entrada comercializados. Em relação aos inibidores da transcriptase reversa, não efectuámos a sua diferenciação em análogos dos nucleósidos, análogos dos nucleótidos e não análogos dos nucleósidos.

Os artigos considerados são os publicados até Dezembro de 2007, visto as publicações datadas de 2008 poderem ainda não estar indexadas na MEDLINE.

Ao longo das três fases da segunda parte do trabalho, verificámos uma diminuição considerável do número de artigos à medida que a complexidade associada à construção das estratégias de pesquisa aumenta.

O número de artigos relativos às reacções adversas associadas aos fármacos inibidores da fusão é muito mais reduzido comparativamente ao número de artigos relativos às reacções adversas associadas aos fármacos inibidores da protease e aos fármacos inibidores da transcriptase reversa, podendo atribuir-se esse facto ao seu aparecimento mais recente no mercado.

Após a construção das equações de pesquisa e consequente obtenção de um determinado número de artigos, o passo crucial do método aplicado consiste no cálculo percentual da sensibilidade e especificidade para cada uma das equações.

Para isso, os artigos foram divididos em dois grupos, um que inclui os artigos directamente relacionados com reacções adversas (“gold standard”) e outro que inclui os artigos não directamente relacionados com reacções adversas.

Com excepção da primeira fase, na qual a quantidade analisada é muito elevada, o número de artigos directamente relacionados com reacções adversas excedeu o número de artigos não directamente relacionados com reacções adversas.

Para além da subjectividade inherente, a divisão efectuada pode ter originado uma omissão inadvertida de artigos importantes devida à selecção dos “*subheadings*” relativos à situação clínica, dentro de um conjunto mais alargado de opções.

A maior sensibilidade obtida correspondeu à equação de pesquisa que inclui a classe farmacológica referente aos fármacos inibidores da fusão e o tipo de estudo referente a estudo de casos (77,0%).

A maior especificidade obtida correspondeu à equação de pesquisa construída com a classe farmacológica referente aos fármacos inibidores da fusão (96,3%).

Na primeira fase, a maior sensibilidade foi obtida com a equação de pesquisa construída com a classe farmacológica referente aos fármacos inibidores da protease (60,3%) e a maior especificidade foi obtida com a equação de pesquisa construída com a classe farmacológica referente aos fármacos inibidores da fusão (96,3%), embora a esta equação esteja associada a menor sensibilidade obtida em todo o trabalho (1,4%).

Na segunda fase, a maior sensibilidade (77,0%) e a maior especificidade (82,5%) foram obtidas com a equação de pesquisa que combina a classe farmacológica referente aos fármacos inibidores da fusão e o tipo de estudo referente a estudo de casos.

Na terceira fase, a maior sensibilidade foi obtida com a equação de pesquisa que combina a classe farmacológica referente aos fármacos inibidores da protease, o tipo de estudo referente a estudo de casos e as palavras-chave relativas à situação clínica referente aos inibidores da protease (70,0%). A maior especificidade foi obtida com a equação de pesquisa que combina a classe farmacológica referente aos fármacos inibidores da transcriptase reversa, o tipo de estudo referente a ensaios clínicos aleatorizados e as palavras-chave relativas à situação clínica referente aos inibidores da transcriptase reversa (89,9%).

Os valores relativos à sensibilidade sofrem uma maior variação (1,4% a 77%) comparativamente aos valores relativos da especificidade (35,2% a 96,3%).

Os valores relativos à sensibilidade atingem o seu máximo nas equações de pesquisa que incluem o tipo de estudo referente a estudo de casos. Nas equações de pesquisa que combinam o tipo de estudo referente a estudo de casos e as palavras-chave relativas à situação clínica, os valores da sensibilidade permanecem altos, mas mais baixos que na situação anterior.

A especificidade aumenta crescentemente nas equações de pesquisa que incluem o tipo de estudo, segundo a ordem estudo de casos < revisões sistemáticas < ensaios clínicos aleatorizados, com exceção das equações de pesquisa construídas, na segunda fase, com a classe farmacológica referente aos fármacos inibidores da fusão, nas quais a especificidade correspondente à equação que inclui o tipo de estudo referente a estudo de casos é mais elevada. A mesma evolução é verificada aquando da introdução das palavras-chave relativas à situação clínica nas equações de pesquisa, sendo os valores obtidos mais elevados comparativamente à situação anterior, com exceção da equação que inclui o tipo de estudo referente a estudo de casos.

Dada a originalidade do trabalho desenvolvido, não encontrámos literatura que aborde, simultaneamente, o mesmo objecto de estudo e a mesma metodologia de pesquisa para comparação e discussão mais detalhada dos resultados.

O recurso à metodologia utilizada foi visível nalguns estudos nos quais se destaca a criação do grupo “*gold standard*” e a obtenção de melhores resultados no que diz respeito à sensibilidade e especificidade. De qualquer modo, observámos múltiplas diferenças: as equações de pesquisa construídas incluem termos MeSH, termos e/ou

expressões recolhidos no título e resumo dos artigos, termos relativos a um único tipo de estudo e o emprego de outros “*subheadings*”; o número de artigos analisados é muito inferior; as bases de dados bibliográficas utilizadas são diferentes e não tão vastas como a MEDLINE, ou quando se recorre a esta, o operador em causa não é a PubMed; o objecto de estudo do trabalho é uma reacção adversa específica de um determinado fármaco, diferente dos fármacos anti-retrovíricos; a validação da metodologia inclui outros instrumentos, como a precisão; entre outros aspectos.

O estudo levado a cabo por Indritz e Artz(188) pretende fazer uma avaliação do “valor” da profissão farmacêutica, com a descrição e documentação desse conceito com cuidados prestados e a informação a outros profissionais de saúde, recorrendo a um método de revisão bibliográfica na MEDLINE e *International Pharmaceutical Abstracts* baseado em combinações de palavras-chave recolhidas em artigos publicados durante um certo período de tempo e na criação de grupos “*gold standard*” para avaliação de determinados itens relacionados com o objecto de estudo.

Wilczynski e colaboradores(189) realizaram um estudo transversal para identificação e avaliação da informação clinicamente relevante de artigos referentes a estudos de prognóstico, comparando a informação obtida, na MEDLINE (operador OVID), através da construção de equações de pesquisa com termos MeSH e palavras do texto, incluídas no título ou resumo do artigo, com uma revisão manual dos artigos presentes em 161 jornais do ano 2000 (“*gold standard*”). Os valores da sensibilidade, especificidade, precisão e exactidão foram calculados, tendo-se atingido picos de sensibilidade e de especificidade da ordem de 90%. Ainda em 2004, os mesmos autores(190) optimizaram uma metodologia de pesquisa de artigos relacionados com estudos de pesquisa de serviços de saúde, com base na adequabilidade, avaliação do processo e do resultado, directrizes da prática clínica, custos e economia da saúde, comparando a pesquisa de termos ou expressões metodológicas na MEDLINE com a pesquisa manual da literatura relativa ao assunto em 68 jornais do ano 2000 (“*gold standard*”). Os valores da sensibilidade, especificidade e precisão foram calculados, tendo-se obtidos valores de sensibilidade que variaram entre 88,1% e 100%, e valores de especificidade que variaram entre 88,8% e 99,8%.

Em 2005, Wilczynski e colaboradores(191) descreveram o desenho e o método de um estudo referente ao desenvolvimento de equações de pesquisa capazes de recuperar informação clinicamente relevante de estudos clínicos de doenças em bases de dados bibliográficas de grandes dimensões como a MEDLINE, EMBASE, CINAHL e PsycINFO. Assim, tendo em conta certos aspectos como o formato do artigo, o seu interesse para os cuidados de saúde, a apresentação dos dados em artigos de revisão, a idade dos indivíduos, o objectivo do artigo e o rigor metodológico, analisaram comparativamente os resultados da pesquisa manual realizada em 170 jornais de 2000 (“*gold standard*”) com a pesquisa realizada nas bases de dados referidas à custa de termos indexados e palavras do texto, para, após o cálculo da sensibilidade, especificidade, precisão e exactidão, criarem uma nova base de dados usada para o desenvolvimento e validação das equações de pesquisa.

Tendo mostrado, em 2003(192), que as revisões sistemáticas são mais citadas que as revisões narrativas, sendo poucos os jornais que publicam a maioria das revisões sistemáticas, Montori e colaboradores(193) publicaram um estudo transversal referente à optimização de uma metodologia de pesquisa para recuperação de revisões sistemáticas na MEDLINE (operador OVID), documentando o artigo os termos utilizados aos quais se associa a melhor sensibilidade, especificidade e precisão. Desse modo, foram calculados os referidos parâmetros, após uma pesquisa de revisões sistemáticas na MEDLINE com equações de pesquisa construídas com combinações de um a cinco termos, e uma pesquisa manual de todos os artigos de 161 jornais publicados no ano 2000 e indexados à MEDLINE (“*gold standard*”). Apesar da percentagem de revisões sistemáticas obtida ter sido baixa, a sensibilidade atingiu um máximo de 99,9% e a especificidade atingiu um máximo de 99,5%.

Recorrendo a revisões da *Cochrane*, Zhang e colaboradores(194) desenvolveram uma metodologia de pesquisa para identificação de ensaios clínicos aleatorizados na MEDLINE, tentando encontrar a melhor equação, ou seja, aquela que apresentasse uma elevada sensibilidade e precisão.

Haynes e colaboradores desenvolveram uma metodologia de pesquisa na MEDLINE (operador OVID) para recuperação de estudos clínicos relativos ao diagnóstico(195) e estudos de prevenção e tratamento de doenças(196), recorrendo à pesquisa manual de 161 jornais publicados em 2000 e indexados na MEDLINE (“*gold standard*”) e ao cálculo da sensibilidade, especificidade, precisão e exactidão de equações de pesquisa com termos isolados ou combinações de termos. Em relação aos estudos de diagnóstico, a maior sensibilidade obtida foi 98,6% e a maior especificidade foi 98,4%, enquanto que, nos estudos de prevenção e tratamento, a maior sensibilidade obtida foi 99,3% e a maior especificidade foi 97,4%.

Golder e colaboradores(197-200) direcionaram a sua investigação para as reacções adversas relatadas em casos clínicos, visto considerarem a pesquisa de informação em relação a reacções adversas problemática e existir pouca evidência acerca dos métodos mais apropriados para o fazer, estando esta mais limitada à informação encontrada em ensaios clínicos controlados aleatorizados.

Num primeiro estudo analisado no qual se denota a necessidade da melhoria no relato de reacções adversas e da sua indexação(197), o objectivo consistiu na avaliação da *performance*, com base na determinação da sensibilidade e precisão, de diferentes abordagens para identificação de estudos relacionados com reacções adversas na MEDLINE e EMBASE (a EMBASE foi escolhida porque pesquisas anteriores mostraram que se trata de uma das melhores bases de dados para obtenção deste tipo de estudo; a MEDLINE foi escolhida devido à grande cobertura de literatura relacionada com este tema e pelo acesso por parte dos profissionais):

- recurso a reacções adversas específicas;
- recurso a “*subheadings*” usados em separado ou em conjunto com o nome do fármaco indexado (no caso da MEDLINE, os usados foram “*adverse effects*”,

“toxicity”, “poisoning” em conjunto com o nome do fármaco, sendo ainda utilizados, em separado, “drug effects” e “complications”);

- recurso a palavras do texto obtidas no título e resumo dos artigos;
- recurso a termos indexadores para “adverse effects” (na MEDLINE, foi usado “drug toxicity”);
- pesquisa para tipos de estudo específicos (“case-control studies”, “cohort studies”, “clinical trials”, no caso da MEDLINE, através da OVID).

A sensibilidade e a precisão destas cinco abordagens e das suas combinações foram comparadas, usando, para o efeito, uma revisão sistemática referente às reacções adversas de sete anti-epilépticos (os resultados de uma única revisão sistemática de um tópico específico constituiu uma limitação do estudo).

Na MEDLINE, a mais alta sensibilidade (89,7%) foi obtida com os “subheadings” não indexados ao nome do fármaco, sendo “adverse effects” o mais significativo. A combinação com maior sensibilidade associada (97%) inclui uma combinação de termos para reacções adversas específicas, “subheadings” não indexados (“adverse effects”, “complications”, “drug effects”) e palavras do texto relativas a “adverse effects”. Uma das razões para não se ter atingido uma sensibilidade de 100% relaciona-se com o facto da MEDLINE não incluir os nomes dos fármacos.

Na EMBASE, a combinação de termos para reacções adversas específicas e palavras do texto relativas a “adverse effects” foi a estratégia com maior sensibilidade (98,6%).

Num segundo estudo publicado por estes autores(198), efectuou-se uma pesquisa metodológica de revisões sistemáticas nas quais o principal assunto diz respeito a uma ou várias reacções adversas, já conhecidas ou suspeitas de o serem, associadas com a intervenção, levada a cabo na DARE (*Database of Abstracts of Reviews of Effects*) e CDSR (*Cochrane Database of Systematic Reviews*), entre 1994 e 2005, tendo sido escolhidas estas bases de dados por abarcarem maior número de revisões sistemáticas.

As estratégias de pesquisa incluíram combinações de palavras de texto recolhidas no título e resumo dos artigos, termos MeSH e “subheadings” (“adverse effects”, “poisoning”, “drug effects”, “complications”, “toxicity”, “chemically induced”), não tendo sido estabelecidos quaisquer restrições em relação à língua.

Os resultados das pesquisas foram introduzidos no programa “Endnote”, tendo sido removidos os duplicados e seleccionados os artigos para inclusão no estudo (dos 3635 artigos obtidos, apenas 257 respeitavam os critérios de inclusão). A suspeita da perda de revisões relevantes com estas estratégias levou a que os artigos não recuperados também fossem analisados, tendo também sido feita uma pesquisa manual na DARE.

Estabelecido o “*gold standard*”, foram calculados os valores da sensibilidade e precisão.

A equação de pesquisa construída com os “*subheadings*” referidos obteve a maior sensibilidade (85% na DARE e 64% na CDSR), sendo a precisão de todas as estratégias mais elevada na DARE (16 a 71%) do que na CDSR (0 a 3%).

As estratégias mais sensíveis incluíam, na DARE, uma combinação de palavras de texto, termos MeSH e “*subheadings*” (94% de sensibilidade e 16% de precisão) e incluíam, na CDSR, a combinação “*adverse effects*” com “*adverse near/20 objectives*” (79% de sensibilidade e 3% de precisão).

As pesquisas manuais na DARE e a análise dos artigos não recuperados confirmaram a suspeita de que foram perdidas revisões relevantes.

As sensibilidades de muitas destas combinações foram comparadas com as encontradas noutros estudos, como é o caso do artigo anterior; sensibilidades similares foram obtidas com a pesquisa com os “*subheadings*” (salienta-se “*adverse effects*”) e termos indexadores, sendo atribuídas as diferenças ao tipo de estudo empregue.

A pesquisa de revisões sistemáticas relativas a reacções adversas, nas principais bases de dados de revisões sistemáticas, mostrou, assim, uma maior dificuldade comparativamente à prevista, devido à falta de terminologia usada pelos autores, indexações inadequadas e variações entre bases de dados.

Nesse sentido, os mesmos autores dos dois artigos anteriores(199) pretenderam determinar quais os aspectos da pesquisa metodológica a ter mais em conta para melhorar as revisões sistemáticas relativas a reacções adversas, fazendo uma análise descritiva das revisões anteriores, tendo em conta o tipo de intervenção estudada, as reacções adversas, as fontes pesquisadas, equações de pesquisa, fontes de dados incluídas nas revisões, avaliação da qualidade dos estudos primários e a natureza da análise dos dados, mostrando este novo estudo uma necessidade óbvia de melhorar a metodologia e o relato de reacções adversas (os aspectos relacionados com a identificação das reacções adversas e a avaliação da qualidade dos estudos são os mais preocupantes). Mais recentemente(200), apresentaram uma avaliação dos métodos usados para identificação de revisões sistemáticas relativas a reacções adversas feita independentemente por dois profissionais com base em 277 revisões da DARE e CDSR que cumprem os critérios de inclusão. Esta investigação mostra variações nos métodos de pesquisa utilizados e enfatiza o relato mais pormenorizado das reacções adversas para melhor compreensão dos leitores para posteriores replicações do processo de pesquisa e uma possível criação de directrizes.

Num último estudo analisado, atendendo à constatação por parte dos autores de que os estudos observacionais (estudos de casos – controlo, estudos de coorte e casos clínicos) se referem a reacções adversas raras ou cujo aparecimento demora muito tempo, Wieland e Dickersin(201) pretendiam explorar o desenvolvimento de possíveis

metodologias de construção de estratégias de pesquisa para identificação de estudos observacionais referentes à associação entre contraceptivos orais e cancro da mama (considerado uma reacção adversa da terapêutica referida), na MEDLINE, considerada uma importante base de dados internacional passível de identificar este tipo de estudo.

Este estudo aborda, assim, reacções adversas específicas, embora, segundo os autores, se possam construir estratégias de pesquisa mais extensas, quando se trata genericamente de reacções adversas.

O “*gold standard*” considerado continha 58 artigos de uma revisão sistemática, publicados antes de 1996 (porque as publicações de 1996 podiam ainda não estar disponíveis na MEDLINE), donde recolheram palavras ou expressões, contidas no título e resumo, e termos MeSH, relacionados com a intervenção, reacções adversas e tipo de estudo. As equações de pesquisa foram, então, construídas, com as palavras do texto e com os termos MeSH, em separado e em associação, sob várias formas, tendo-se também estudado a contribuição do tipo de estudo e da intervenção com a construção de novas estratégias que omitiam os termos referentes a tais itens.

O texto integral de cada artigo não obtido com as estratégias de pesquisa foi também examinado com vista à possível determinação da sua forma de recuperação.

O cálculo da sensibilidade e precisão foi efectuado para cada uma das estratégias de pesquisa.

A equação de pesquisa mais precisa (11% com termos MeSH e 39% com palavras do texto) incluiu a combinação com termos relativos à intervenção, reacção adversa e tipo de estudo, mas a mais sensível (100% com termos MeSH e palavras do texto) foi a equação onde se omite termos relativos à intervenção. As equações que contêm palavras do texto são menos precisas que aquelas que contêm termos MeSH. As combinações de termos MeSH e palavras do texto não melhoram a sensibilidade. Estudando a contribuição da intervenção e tipo de estudo, nas equações onde se omite o tipo de estudo, a precisão diminui sem melhorar a sensibilidade e, naquelas onde se omite a intervenção, a precisão também diminui, mas alcança-se 100% de sensibilidade.

Como limitações do estudo, são referidas a indexação limitada de termos MeSH relativos à intervenção e a publicação incompleta de dados nos estudos observacionais.

Mais uma vez, os autores recomendam a necessidade de uma melhoria do relato dos dados relativos à intervenção e reacções adversas nos estudos observacionais para um fortalecimento da transparência, replicabilidade e validade das revisões sistemáticas de reacções adversas, acreditando que a criação de orientações direcionadas para este assunto possa ser benéfica (apesar de, neste estudo, a identificação dos estudos relevantes com as equações de pesquisa utilizadas ter sido possível, é necessária mais investigação para uma possível generalização).

CAPÍTULO V



CONCLUSÕES

Os valores de sensibilidade e especificidade obtidos com as diferentes equações de pesquisa construídas mostram que os objectivos propostos de optimização de uma metodologia sistematizada de pesquisa bibliográfica relativa a resultados clínicos negativos da terapêutica anti-retrovírica foram cumpridos, salientando-se a importância do filtro qualitativo relativo ao tipo de estudo, uma vez que a informação pretendida é encontrada, fundamentalmente, em casos clínicos referenciados na literatura.

O trabalho desenvolvido, inédito na área da infecção VIH / SIDA, vem comprovar e reforçar a real necessidade de uma gestão do risco dos resultados clínicos negativos da terapêutica, dependente grandemente da relação estabelecida entre o profissional de saúde e o doente.

Possíveis passos a seguir com vista à melhoria dos resultados obtidos seriam a consulta dos processos clínicos dos doentes acompanhados numa determinada instituição hospitalar para análise das reacções adversas relatadas, e o contacto directo com os profissionais de saúde especializados nesta área para obtenção de sugestões de termos ou expressões empregues na sua prática diária, a utilizar futuramente na construção de equações de pesquisa mais sofisticadas, nas quais se pudesse incluir também novos filtros metodológicos.

A maior disponibilidade de informação contribui para uma avaliação criteriosa da qualidade da literatura científica traduzida na sua fiabilidade, clareza, objectividade, validade e aplicabilidade; daí a importância crescente do conhecimento e aprendizagem da procura da evidência em fontes credíveis que, conjugada com o sentido crítico individual, serve de suporte à decisão clínica, reflexo do serviço prestado ao doente.



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