

achieved. It is true that as physicians we prefer “positive” trials because they leave us with a sense of a conclusive message. However, both the AFFIRM² and Van Gelder and associates⁵ trials did yield a conclusive and important message, that for presently available approaches to atrial fibrillation therapy, rate control is not inferior overall to rhythm control. It is debatable whether larger studies that achieved a statistically significant *p* value would have provided any more practical information.

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First-use risks

Eric Wooltorton¹ has written a balanced article in response to the warning on Diane-35 and the risk of venous thromboembolism issued by Health Canada.

Caution is always required in prescribing estrogen-progestin combinations, whether for contraception, postmenopausal hormone replacement or treatment of acne. However, the risk attributed to preparations containing cyproterone acetate in comparison with other preparations may have been exaggerated by not taking first-time use into

account. This effect has been estimated² to increase the risk of venous thromboembolism 10-fold in the first year of oral contraceptive use, regardless of preparation. The research letter of Vasilakis-Scaramozza and Jick,³ which was used by Health Canada to support the increased risk, provided adjusted odds ratios for venous thromboembolism, but no reference is made to first-time use as a potential factor. That report described a total of 128 subjects (cases and controls) who had used levonorgestrel-containing preparations and 42 subjects (cases and controls) who had used preparations containing cyproterone acetate. In the first group, only 9 (7%) had used the preparation for 6 months or less, whereas in the second group, a much larger proportion (12 or 29%) had used the drug for 6 months or less. Among patients with this short duration of use, there is a greater probability of first-time use. Thus, the proportion of women using an estrogen-progestin combination for the first time appears to have been higher in the group receiving preparations containing cyproterone acetate, which might account for some or all of the greater risk of venous thromboembolism in that group.

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QALYs: the best option so far

Iwould like to challenge Maurice McGregor's argument in a recent commentary¹ that because the quality-

adjusted life-year (QALY) has “severe limitations,” it is not useful for cost-utility analyses.

To support his argument that the QALY is not meaningful, McGregor quotes a seminal work emphasizing the difficulty of using a single measurement to evaluate different health outcomes.² However, this same text recommends the continued use of the QALY while researchers develop potentially better tools.³

McGregor also argues that the QALY is not valid because it “frequently violates societal concerns for fairness in the allocation of health care resources.” Such ethical concerns have been expressed before, but alternatives to circumvent them are still relatively nascent, and “the conventional QALY remains the dominant approach.”²

McGregor then contends that the QALY is not reliable because utility estimates vary with the method used. However, variability can occur in any research. Consider how frequently clinical studies yield conflicting results. A more pertinent question is whether this variability is truly fatal to interpreting cost-effectiveness analyses.

McGregor next argues that the QALY is not relevant because there is “no unanimity as to whose viewpoint should be used when making societal policy decisions.” This does not make the QALY irrelevant — it merely means that research is needed to clarify the issue.

McGregor's final argument is more a general cautionary statement: “When the studies with which the cost-utility analysis in question can be compared are not identified, the cost-utility analysis should clearly not be used in health policy decisions.” However, the same can be said in any field: comparators should always be identified. Furthermore, comparing one cost-effectiveness ratio with another is no different from using league tables based on number-needed-to-treat to evaluate the clinical effectiveness of interventions.³

Without doubt, the QALY is an imperfect outcome measure. Nonetheless, despite acknowledging its weaknesses,