Cost-effectiveness and contraceptive effectiveness of the transdermal contraceptive patch
Sonnenberg F A, Burkman R T, Speroff L, Westhoff C, Hagerty C G

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The transdermal contraceptive patch and low-estrogen-dose (less than 50 microg) combined oral contraceptives (COCs) were examined. The patch was assumed to deliver 150 microg norelgestromin and 20 microg ethinyl estradiol daily to the systemic circulation.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a hypothetical cohort of women aged 15 to 50 years and of average health, who were in a long-term, mutually monogamous, heterosexual relationship. The analysis excluded overweight women (body mass index greater than 25) and those at higher-than-average risk of breast cancer (e.g. positive family history) or with a history of clinical cardiovascular or thromboembolic disease.

Setting
The setting was primary care. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness data came from studies published from 1989 to 2004. No dates for the resource use data were explicitly reported. The price year was 2002.

Source of effectiveness data
The effectiveness evidence was derived from a synthesis of completed studies and authors' opinions.

Modelling
The authors stated that a published decision model was used to examine the costs and clinical outcomes associated with COCs and patches in a hypothetical cohort of healthy women. A Markov model was used with a time horizon of 2 years. Monte Carlo simulation was carried out for 100,000 iterations. The model applied only to women not attempting to become pregnant during the time horizon of the analysis. The use of contraceptives was continuous unless a clinical event (pregnancy or development of a clinical complication) necessitated discontinuation. After diagnosis of any condition that contraindicated further hormonal use, patients stopped the use of all hormonal contraceptive methods and adopted a non-hormonal method. The model also considered no contraception and other methods of contraception. No further information was provided.
Outcomes assessed in the review
The outcomes estimated from the literature were age-specific pregnancy rates for the patch and COC, and the percentage of perfect cycles (perfect-dosing cycles) with the two strategies.

Study designs and other criteria for inclusion in the review
It was unclear whether a systematic review of the literature was undertaken. It appears that the primary studies have been identified selectively. Some data appear to have been derived from clinical trials but few other details were given.

Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
The use of randomised clinical trials (RCTs) ensures the validity of some primary sources. However, only two RCTs appear to have been used. The design of the other sources was not described.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
Five primary studies appear to have provided the evidence.

Methods of combining primary studies
The rate of pregnancy with the patch was calculated by adjusting the rate of pregnancy for COCs found in the literature by the relative rate of perfect cycles of the two strategies.

Investigation of differences between primary studies
Not stated.

Results of the review
The rate of perfect cycles was 88.7% with the patch and 79.2% with COCs, (p<0.001).

There was no statistically significant difference between the two strategies in terms of contraceptive efficacy.

Adjusting the contraceptive efficacy of the two strategies by the rate of perfect cycles, the annual age-specific pregnancy rates were:

- 0.131 with COCs and 0.075 with the patch in the age range <20 years;
- 0.083 with COCs and 0.055 with the patch in the age range 20 - 24 years;
- 0.048 with COCs and 0.036 with the patch in the age range 25 - 29 years;
- 0.048 with COCs and 0.041 with the patch in the age range 30 - 34 years;
- 0.032 with COCs and 0.026 with the patch in the age range 35 - 39 years;
- 0.032 with COCs and 0.025 with the patch in the age range of 40 years and older.
The annual probabilities of pregnancy with no contraceptive method or the diaphragm were also reported.

Methods used to derive estimates of effectiveness
Assumptions were made to derive some effectiveness estimates. In addition, an expert panel was convened to review the literature of contraception and to determine all factors considered important in when choosing a contraceptive method.

Estimates of effectiveness and key assumptions
Menopause occurred at a mean age of 51 years, and women discontinued any contraceptive method at that time and had a zero risk of subsequent pregnancy. The risk of pregnancy was zero after total abdominal hysterectomy. The relative risks of developing a medical condition were the same for both the patch and COCs.

Measure of benefits used in the economic analysis
The summary benefit measure used was the reduction in the number of pregnancies due to patch in comparison with COCs. It was derived using a modelling approach. No discount rate was applied.

Direct costs
The perspective adopted in the study was not explicitly stated, although the costs might have been assessed from the perspective of a private insurer. The health services included in the economic evaluation were contraceptive methods (patch, COCs, diaphragm, condoms and intrauterine devices), and the treatment of medical events and complications. Medical events and complications covered cancer (breast, cervical, endometrial and ovarian cancer), cardiovascular events (myocardial infarction, stroke, venous thromboembolic disease), infection (AIDS and urinary tract infection), menstrual-related disorders and pregnancy (different routes of delivery, abortion and newborn). The costs of the tests were reported. However, the unit costs of complications and medical events were not presented separately from the quantities of resources used as the costs were reported as macro-categories. The bulk of the costs came from a nationwide sample of privately insured individuals for both ambulatory and hospitalised patients. The cost of contraceptives was estimated using average wholesale prices, weighted according to the fraction of the market share. A modelling approach was used to derive the total costs associated with the two strategies under examination. All the costs were inflated to 2002 using the Consumer Price Index. Future costs were discounted at an annual rate of 3%.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
The indirect costs were not considered.

Currency
US dollars ($).

Sensitivity analysis
A univariate sensitivity analysis was carried out to examine the impact of changes in age of the cohort, time horizon, number of imperfect cycles per year and cost of COCs, on savings and pregnancies avoided. Alternative values were derived from the literature or were set by the authors.

Estimated benefits used in the economic analysis
The use of the patch led to 0.03 pregnancies avoided per woman in comparison with COCs over 2 years.
Cost results
The use of the patch resulted in a saving of $249 over COCs. The cost-savings were due to avoided pregnancies. The total costs for COCs, patch and no contraceptive method were depicted graphically only. The largest proportion of the costs for the patch and COCs were attributed to the method (52% and 47%, respectively), while for no contraceptive method, 98% of the costs were due to the pregnancy.

Synthesis of costs and benefits
The costs and benefits were not synthesised because the use of the patch was more effective and less costly than COCs.

The sensitivity analysis showed that savings and pregnancies avoided decreased with increases in age. In addition, there was a generally inverse relationship between cost-savings and age. Moreover, savings and pregnancies avoided with the patch increased when the time horizon was increased.

As the number of imperfect cycles with COCs was increased, the cost-savings with the patch and the number of pregnancies avoided per woman increased. The threshold above which the patch was cost-saving was 1.22 imperfect COC cycles per year, while the threshold above which the patch resulted in a net avoidance of pregnancy was 1.39 imperfect COC cycles.

When the price of COCs exceeded the threshold of $25.90 per cycle (base-case $45), the use of the patch was cost-saving. Thus, the base-case results held even if the COC cost was based on generic pricing.

Authors' conclusions
The use of the patch was cost-saving in comparison with the use of combined oral contraceptives (COCs). It resulted in fewer pregnancies for a population of healthy women aged 15 to 50.

CRD COMMENTARY - Selection of comparators
The selection of the comparators was appropriate and was consistent with the objective of the study. A combination of oral contraceptives was used to reflect standard care. The authors stated that both contraceptive methods under evaluation were compared with a hypothetical reference case of no contraceptive method. Alternative contraceptive approaches were also considered in the decision model (diaphragm and copper intra-uterine device). You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from published data. The primary studies were presumably identified selectively. The methods used to calculate the clinical estimates from published data were reported. Most of the evidence came from clinical trials, although some assumptions were made. The authors stated that their analysis relied on a summary interpretation of one of the RCTs, which was carried out in North America. In particular, the analysis assumed the inherent equal efficacy of the two contraceptive methods but hypothesised that, in actual use, the effectiveness of the patch would exceed that of COCs. Such a key assumption was not explicitly taken into consideration in the sensitivity analysis, although it was noted that the modelled effectiveness was a reasonable interpretation of trial data.

Validity of estimate of measure of benefit
The summary benefit measure was specific to the interventions considered in the study. It is not comparable with the benefits of other health technologies. The impact of the interventions on quality of life was not investigated. In addition, the authors stated that the impact on mortality was negligible and only small effects on utility decrements were observed.

Validity of estimate of costs
The perspective adopted in the study could have been that of a health insurer, although it was not explicitly stated. Clear information on the unit costs and quantities of resources used was provided in relation to the contraceptive strategies. However, the costs associated with the treatment of complications and other medical events were presented as grouped categories, thus a detailed breakdown of the cost items was not reported. The costs were treated deterministically and only some key cost estimates were varied in the sensitivity analysis. The source of the data was provided. The price year was reported, which aids reflation exercises in other time periods. The authors noted the limitations of using cost data from a large administrative database as a proxy for costs.

Other issues
The authors did not make extensive comparisons of their findings with those from other studies. They also did not explicitly address the issue of the generalisability of the study results to other settings. Some sensitivity analyses were carried out, which enhance the external validity of the analysis. The results of the analysis were presented selectively. The total costs and the estimated number of pregnancies were depicted graphically only. The authors noted some limitations of their analysis, which have been highlighted already.

Implications of the study
The study results support the use of the transdermal contraceptive patch in healthy women.

Source of funding
Funded by an unrestricted educational grant from Ortho-McNeil Pharmaceutical Inc.

Bibliographic details

PubMedID
15671994

DOI
10.1016/j.ajog.2004.09.004

Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
Administration, Cutaneous; Administration, Oral; Adolescent; Adult; Contraceptive Agents, Female /administration & dosage /economics; Contraceptives, Oral, Combined /administration & dosage /economics; Cost-Benefit Analysis; Female; Humans; Middle Aged; Models, Econometric; Pregnancy; Pregnancy Rate; United States

AccessionNumber