

Hygroscopic dilator (Dilapan-S™) and misoprostol combination for the early first-trimester termination of pregnancy: a pilot study

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Abstract

Background and methodology Uptake of the mifepristone/ misoprostol combination to induce early medical abortion in England and Wales has been slow. Women's concern that early medical abortion is painful may be a contributory factor. This pilot study evaluated the pain experienced by women when Dilapan-S™, a synthetic hygroscopic dilator (polyacrylonitrile) is used instead of mifepristone as cervical preparation prior to administration of a misoprostol.

Results Of 25 patients completing the trial, 17 aborted in

a median of 6 hours with an interquartile range of 4.5–11.5 hours. Of these, 15 patients recorded mild discomfort only, 14 considered the procedure excellent and three good.

Discussion and conclusions This study suggests that the Dilapan-S/misoprostol combination reduces the pain associated with early medical abortion. Further investigation of the protocol is merited.

Keywords Dilapan-S™, early medical abortion, mifepristone, misoprostol, pain in abortion

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Introduction

Medical termination of pregnancy (TOP) using a combination of anti-progesterone (mifepristone) and a prostaglandin has been slow to gain popularity in England and Wales, though recently there has been an increase in uptake. The experience in Scotland where uptake has been better suggests that increasing provision and promotion of the method has a positive impact. A significant number of women experience pain during medical TOP,^{1,2} which may deter some women from opting for this procedure.

Mifepristone is an anti-progestogenic steroid that sensitises the myometrium to prostaglandin-induced contractions and ripens the cervix. Dilapan-S™ (Figure 1), a hygroscopic mechanical dilator (Gel-Med International, spol. sr.o., Karlovarska 20, Kamenne Zehrovice, CZ 273 01, Czech Republic/PO Box 65, St Albans, Herts AL3 8EQ, UK) may be used to prepare the cervix before TOP. This device is used routinely prior to second-trimester dilatation and evacuation at King's College Hospital, London, UK. Inserted 4–24 hours prior to TOP, it absorbs fluid and painlessly dilates the cervix. The hypothesis was that prior cervical preparation with Dilapan-S followed by misoprostol would be more effective and therefore less painful than the mifepristone/misoprostol combination. There are no reported studies comparing the effect of mifepristone and Dilapan-S on the cervix. As a first step the pain experienced by women during abortion using the Dilapan-S/misoprostol combination was assessed. There are no reports in the literature of this combination being used to cause medical abortion in pregnancies of less than 9 weeks.

This communication reports a pilot study that could be taken forward to a randomised study to compare the use of Dilapan-S/misoprostol with mifepristone/misoprostol in the induction of abortion.

Key message points

- Reduction of pain in medical abortion may further improve the acceptability and uptake of early medical abortion.
- This pilot study suggests that a Dilapan-S™/misoprostol combination reduces the pain associated with early medical abortion.
- A full randomised trial of the Dilapan-S/misoprostol combination is therefore merited.

Methods

Provided there were no medical contraindications (i.e. cerebrovascular disease, coronary artery disease, peripheral vascular disease, known allergy to prostaglandins,



Figure 1 Dilapan-S™, a synthetic hygroscopic mechanical dilator, before and after cervical insertion

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untreated pelvic infection or a patient aged under 16 years) suitable patients referred to the King's College Hospital termination counselling clinic were offered the procedure if they were less than 64 days' pregnant (crown-rump length <22 mm) as an alternative to suction TOP under general anaesthesia or medical TOP with mifepristone/misoprostol.

All patients were given an information sheet describing the purpose of the pilot study and the procedure was explained by a nurse counsellor. Those opting to be included in the study were then seen by a doctor to confirm that they understood the information they had been given. It was made clear that if the procedure did not result in a complete abortion by 2.00 pm on the day of the termination then the patient would be placed on a routine operating list for a surgical TOP under general anaesthesia that day. The patient then signed a consent form.

On the afternoon before the planned abortion a 4 mm hygroscopic dilator was inserted into the endocervical canal through the internal cervical os. This was done by first passing a Cusco speculum to expose the cervix. The dilator was grasped using sponge-holding forceps by the threaded end and gently pushed through the endocervical canal until the operator felt that it had passed through the internal os.

The first five patients placed 800 mg misoprostol intravaginally at 6.00 am on the day of the abortion. The subsequent 21 patients placed 400 mg misoprostol intravaginally at 8.00 pm on the day the Dilapan-S was inserted and 400 mg at 6.00 am the following morning.

The women were admitted to the ward at 8.00 am. To control pain analgesics were given depending on the pain score. Patients who had no discomfort were given no analgesia. Those who had mild discomfort were offered paracetamol 1 g orally. Those with moderate discomfort were offered dihydrocodeine 30–60 mg or co-dydramol (paracetamol 500 mg + dihydrocodeine tartrate 10 mg) two tablets 4-hourly orally. Those who had severe unbearable pain were given pethidine 50–100 mg intramuscularly. To control nausea/vomiting patients were given prochlorperazine 12.5 mg intramuscularly 4-hourly as required.

The time from first administration of misoprostol to a successful abortion was recorded. Pain was scored by the patient on a scale of 0 to 10. The scores were defined as follows: 0 to 5 – nil to slight pain, 6 to 8 – moderate pain, 9 to 10 – severe pain. Patient satisfaction, side effects and the place of abortion were recorded.

Where the doctor was in doubt regarding the completeness of the termination procedure a vaginal scan was undertaken. All patients were followed up 2 weeks later and assessed prior to discharge from care.

Ethical approval

The study was approved by the King's College Hospital Ethics Committee.

Results

A total of 26 patients were recruited to the study. One patient withdrew after the insertion of the Dilapan-S and requested a surgical TOP. Of the remaining 25 patients, 17 aborted completely within 2–17 hours (median time 6 hours, interquartile range 4.5–11.5 hours) of the first dose of misoprostol. Dilapan-S was expelled in all of those that miscarried. Two women aborted incompletely and six did not abort before the 3.00 pm deadline (i.e. 18 hours after the administration of misoprostol).

Of the 17 patients aborting completely, 15 recorded mild discomfort. One patient complained of moderate pain and one severe pain, both of whom were given co-

dydramol as analgesia in hospital. Pain was reported to be highest at the time of expulsion of the products of conception.

Of the 17 cases who aborted, 14 considered the procedure to be excellent and would recommend it to others. The remaining three patients (including the two reporting more than mild discomfort) considered the procedure to be good but did not commit themselves as to whether they would recommend it to others.

Of the 25 patients taking part in the study, eight reported diarrhoea, one vomiting, three nausea and two headache.

Discussion

The earlier a TOP is performed the safer it is for the woman, therefore ways of making early medical abortion more appealing are of interest. The incidence of significant pain is difficult to assess from the published literature on early medical abortion. Spitz *et al.* studied 2121 women in 17 centres in the USA.³ Nearly all complained of abdominal pain and approximately half complained of severe pain. Westhoff *et al.* studied the predictors of analgesia use in the same group of women and concluded that the most important determinant was the clinic that provided the care during the abortion.⁴ Of the women they studied, 27% received narcotic analgesia (co-dydramol).⁴ Ashok *et al.* reported the analgesic requirements of 3146 women; 58.6% required oral analgesia (co-dydramol) and 4.7% required parenteral opiate analgesia.⁵

This pilot study was performed to investigate the hypothesis that a Dilapan-S/misoprostol combination was effective and less painful than mifepristone followed by misoprostol. A single dose of misoprostol 36–48 hours after mifepristone leads to a complete abortion in approximately 95.0–97.5% of cases. Misoprostol alone has been used for early medical abortion, and with repeated doses over 1 to 3 days successful termination may occur in over 90% cases.⁶

This protocol only allowed 18 hours between insertion of the first dose of misoprostol and a decision to send the patient for surgical TOP if abortion was not complete. This was because the investigators did not wish to put pressure on the already stretched availability of operating space for emergency evacuation of retained products of conception and to ensure that volunteers to the study did not have to wait unduly for their abortion to be complete. Had a longer period been available before surgical TOP was performed and further doses of misoprostol been given then the proportion of successful abortions is likely to have been higher. In retrospect, the women who had not aborted could have been offered suction TOP or manual vacuum aspiration with or without local anaesthesia as their cervixes would not have required dilatation.

The majority (15/17) of the women who aborted complained of mild discomfort, one complained of moderate and the other severe pain. The numbers in the study were small but the authors feel the data are encouraging. There were no complaints following the slight pain on insertion of the Dilapan-S.

Dilapan-S (4 mm) costs approximately £6.00 and needs a nurse or doctor for insertion whilst mifepristone 200 mg costs £13.94 and is taken orally. Taking into consideration the labour costs associated with the use of Dilapan-S, the Dilapan-S/misoprostol combination is more expensive but if the women attracted to this technique were to have had suction TOP there would be a cost saving. Some women opting for early medical abortion may do so because they wish to avoid medical interference and, when offered the option to have pain reduced by Dilapan-S preparation of

their cervix, may still prefer to take the chance that the pain they may experience will be significant rather than have the Dilapan-S inserted.

Conclusions

This pilot study suggests that the Dilapan-S/misoprostol combination reduces the pain associated with medical TOP. Future studies should address the efficacy and cost-effectiveness of this combination in comparison to mifepristone/misoprostol and surgical TOP.

Statements on funding and competing interests

Funding None identified.

Competing interests None identified.

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BOOK REVIEWS

Oxford Handbook of Reproductive Medicine and Family Planning (Oxford Handbooks Series). Enda McVeigh, Roy Homburg, John Guillebaud. Oxford, UK: Oxford University Press, 2008. ISBN-13: 978-0-19-920380-2. Price: £24.95. Pages: 456 (paperback)

This is a well-written handbook by renowned experts that provides a concise, practical and evidence-based coverage of the subject. The format makes it easy to read and, like most good books, the information is conveyed in a logical sequence. Sad as this may sound, it made an enjoyable morning read for me while enduring the daily ordeal of using the London underground!

The book is rightly divided into two parts: reproductive medicine and family planning. This probably underscores the very wide scope of the subjects and also the reality of their actual practice. The first part begins with developmental origins, sexual differentiation, biochemistry and steroidogenesis. This is followed by a description of the physiology of puberty and adolescence, menstrual disorders, the ovaries and disorders of function, as well as the menopause. However, a big chunk of this part is devoted to infertility—nine out of its eighteen chapters – and covers the initial advice, investigations, management strategies and assisted reproductive technology.

The second part of the handbook deals with family planning. I thought the chapter on the combined oral contraceptive pill was particularly enlightening and quite detailed. It provides a good account of the topic, balancing the benefits versus the risks, highlighting practical prescribing issues, counselling and ongoing supervision, drug interactions and fertility considerations. There was also brief mention of transdermal and transvaginal combined hormonal contraception, with the inherent advantages of these routes of administration. A chapter on special considerations outlines how a provider can ensure a woman is not pregnant, and includes useful information on contraception at the climacteric. The appendix highlights the use of licensed products in an unlicensed way, essential websites in reproductive health, further reading suggestions and references.

I have read some of the other Oxford Handbooks Series titles, and I suspect this would certainly rank among the better ones. It would be of interest to trainees and practitioners of reproductive medicine and family planning, students and general practitioners.

Reviewed by **Obinna Mba**, MBBS, DFRSH
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Caring for Muslim Patients (2nd edn). Aziz Sheikh and Abdul Rashid Gatrads (eds). Oxford, UK: Radcliffe Publishing Ltd, 2008. ISBN-13: 978-1-85-775812-2. Price: £24.95. Pages: 158 (paperback)

This book provides an excellent account of very practical and common issues from the perspective of a Muslim patient encountered daily in primary and secondary care.

The early chapters discuss the human condition in the context of Islam with special reference to health issues around cooking and cleanliness. The concept of religious ethic in decision-making and the fact that Muslims will firmly believe in Allah being the supreme healer is highlighted in this book.

Same-sex clinicians, dress code, contraception, fasting and other religious concerns are all discussed, giving valuable insight into what clinicians need to be aware of when managing Muslim patients. All this is set against the backdrop of a very informative account of diversity within British Muslims and the early economic migration from different continents that shaped subsequent distribution of the 2 million or so Muslims in the UK today.

Transcultural perspectives around birth rituals, bereavement, circumcision and organ donation are discussed in line with the expectations of Muslim patients.

The chapter on the Muslim patient is particularly useful as it addresses a lot of day-to-day yet somewhat controversial issues around which many Muslims may have preconceived religious or cultural beliefs (e.g. gender segregation, intermarriage and elderly care). The topics of marriage and the family unit and its central role in Islamic society are elaborated well. Religious ceremonies and issues around prayer and Hajj are also discussed in an informative way. This will certainly provide all those who read this book with much-needed information on understanding this substantive group of patients.

The book should help bridge the gap and thus improve trust and understanding between patients and health care professionals. It also provides useful evidence from the 2001 census, which clearly showed the health inequalities suffered by the Muslim population. This is linked to poor housing and education in these areas.

I thoroughly recommend that all health professionals take time to educate themselves by reading this book.

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Caring for Hindu Patients (2nd edn). Diviash Thakrar, Rasamandala Das, Aziz Sheikh (eds). Oxford, UK: Radcliffe Publishing Ltd, 2008. ISBN-13: 978-1-85-775598-5. Price: £24.95. Pages: 142 (paperback)

Hindus form a significant proportion of the ethnic minority society in Britain today. Health care professionals in all settings and locations need an awareness of their beliefs and cultural expectations, to communicate effectively and provide care in an appropriate manner. This book provides that information in a concise and practical form. It gives a brief overview of the way of life that is now called 'Hinduism'. The first section of the book describes issues relating to language, dress, diet and festivals, as well as traditions and customs that form an integral part of Hindus living anywhere in the world. The second section deals with issues relating to health care. Chapter 5 (marriage and family life) is the most important chapter for clinicians working in sexual and reproductive health since it focuses on marriage, family structure, sex, contraception, abortion, infertility and adoption.

The book illustrates different health care-related situations where tradition and beliefs have an impact not just on how care is delivered but also how it is received and integrated within daily life. It includes case studies to bring to the reader's attention the health-related significance of the topic being discussed. There is also a chapter on death, which enhances the reader's understanding of Hindu approaches to death, to help medical and nursing staff offer care sensitive to the needs of Hindu patients – needs that extend well beyond the immediate and the physical, and encompass longer-term emotional and spiritual requirements. The appendix includes a chapter detailing a variety of websites relating to Hindu practices and traditions and a chapter on diet and weight loss for vegetarian Hindus. This book will help clinicians understand their patients better and therefore become better partners in their health care too.

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