Title: Randomised trial of an integrated educational strategy to reduce investigation rates in young women with DUB

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Funding Source: National Health & Medical Research Council

Footline: educating clinicians about DUB

Abstract

Objectives

To assess the effectiveness of an integrated educational strategy to change clinician behaviour and reduce the number of hysteroscopies and/or dilatation and curettages for women 40 years or less with dysfunctional uterine bleeding (DUB).

Design

Randomised controlled trial with 6 month follow up

Setting

Public teaching hospital gynaecology units. 12 – 13, 000 relevant procedures per year.

Participants

6 public gynaecology units made up of 62 gynaecologists or trainees allocated at random to intervention (3) or control (3) group.

Intervention

An educational strategy that included dissemination of evidence based guidelines via a problem based interactive workshop facilitated by an opinion leader and a laminated algorithm and guidelines.

Main Outcome Measures

The number of hysteroscopies and/or dilatation and curettages performed for DUB on women 40 years or less, clinician behaviour change and perceived booking rates of the procedure.

Results

At 6 months, there was no significant effect on the number of hysteroscopies and/or dilatation and curettages performed but there was an increase in evidence based behaviour.

Conclusions

Whilst the evidence based educational strategy for the appropriate investigation of young women with DUB resulted in clinician behaviour change when applied to theoretical cases, it did not result in a reduction in hysteroscopy/D&C rates at 6 months.

(220 words)

Key words educational strategy, behaviour change, dysfunctional uterine bleeding, diagnostic hysteroscopy, D&C

Introduction

Diagnostic hysteroscopy and/or dilatation and curettage in women less than 40 years is largely an inappropriate and unnecessary investigation.¹⁻⁵ This relates to the very low rates of endometrial carcinoma, (less than 0.17%³) and hyperplasia, (less than 2.7%⁶) detected in women less than 40 years.⁷ Three to 4000 dilatation and curettages would need to be performed to diagnose one case of endometrial cancer in a woman under the age of 35 years.⁸ Risk based assessment using weight, parity and associated factors should inform the need for further investigation in these younger women.^{6,9-11}

Despite this evidence and the efforts to disseminate the research findings, rates of hysteroscopy and curettage in young women remain high.^{2,12-14} Resistance to behavioural change is a common finding with health care providers.^{15,16} Greatest effectiveness in behavioural change is achieved when an integrated approach is adopted using several educational strategies.^{17,18} In particular, clinical guidelines that are easily identified and user friendly can be one form of written material that can change clinical practice,¹⁹ especially when local circumstances are taken into account, and they are disseminated by an interactive educational intervention (eg workshop).^{17,18,20,21} In addition, the use of opinion leaders has had some success with obstetricians.^{22,23}

When exploring effective strategies in the promotion of best practice in the management of dysfunctional uterine bleeding in young women, studies suggest that educational strategies aimed at changing clinician practice in the use of investigations appear to be more successful.²⁴ However, research directly related to dissemination strategies of evidence based guidelines for the management of abnormal uterine bleeding is limited. One study of general practitioners in England demonstrated that an educational package involving visual presentation of evidence (interactive workshop), written material in the form of a printed reference summary, a flow chart for menorrhagia management (clinical guidelines) and a follow-up visit at 6 months resulted in fewer referrals to gynaecologists of women with menorrhagia.²⁵ A combination of evidence based guidelines, a problem based interactive

workshop with an opinion leader has not been reported previously in this area, particularly in the context of attempting to change specialist clinical practice.

This study therefore aims to assess the effectiveness of an integrated educational strategy to change clinician behaviour and reduce the number of diagnostic hysteroscopies/dilatation and curettages for women 40 years or less with dysfunctional uterine bleeding (DUB).

Subjects and methods

A randomised controlled trial was conducted to assess whether an integrated educational strategy including evidence-based guidelines, interactive workshops and an opinion leader would change gynaecologist behaviour resulting in reduced hysteroscopies and/or dilatation and curettages on young women with DUB after 6 months.

Intervention

Public teaching hospitals with gynaecology services were targeted as women with menstrual problems represent 21-25% of all consultations in gynaecology outpatient clinics.^{26,27} The educational strategy included dissemination of evidence based guidelines via a problem based interactive workshop. Participants also received a laminated evidence based management algorithm for dysfunctional uterine bleeding and written material including problem examples. The guidelines utilised a risk assessment model and flow chart modified from the New Zealand recommendations.⁶ As the participants were unable to nominate a particular opinion leader in this area, a modified model of opinion leader was used. This involved selecting a well-respected gynaecological oncologist with the assumption that many specialists and trainees would potentially over investigate this condition for fear of missing hyperplasia or malignancy. The opinion leader co facilitated the workshops. Non attendees of the workshop received all of the educational material in an information kit.

Trial design

A randomised controlled population study was performed where the unit of randomisation was a public teaching hospital department of gynaecology in metropolitan Adelaide. A random one month review of gynaecology outpatient episodes at one of the teaching hospitals demonstrated that women 40 years or less with DUB made up 19% of gynaecology new referrals consistent with rates elsewhere. Pre study procedural rates and means were collected for each of hospital from July to December 1998. (pre test). The study was conducted from April to December 1999. The educational strategy (intervention) was conducted in June 1999, 2 months after recruitment and completion of the initial questionnaire. Behavioural outcome data was collected at 5 months and clinical outcome data was collected over 6 months post intervention.(post test)

The study population of gynaecology departments and their service were examined for heterogeneity prior to randomisation. Variables considered were % of inpatient admissions for menstrual disorders and benign uterine disease, outpatient episodes for benign uterine conditions and clinician profile. Two hospitals with similar characteristics were initially matched and then randomisation occurred by an independent 3rd party by selection of an opaque envelope. The number of D&Cs and/or hysteroscopies performed in the study age group at the population hospitals was static for the previous 6 years at 1200 –1300 procedures per annum.

Whilst this study involved the entire population cluster sample size calculations for the primary outcome measure were performed. Cluster sampling of 6 clusters with an intercluster correlation of 0.02 for an expected difference in mean numbers of procedures per hospital unit of 15% was calculated. Sixteen individual gynaecologists in total and at least 3 per clustered hospital would be required for 80% power at the 0.05 significance.

Participants

The study population were specialists and trainees providing public gynaecology services in the 6 public teaching hospitals in metropolitan Adelaide. All clinicians actively providing gynaecology services over the study period were eligible for entry. Clinicians were assigned to the control and intervention arms according to the result of the hospital randomisation. All clinicians providing public gynaecology services were only affiliated with one metropolitan teaching hospital. No formal guidelines for management were currently available in any of the units and all units provided services for procedural investigation of DUB.

Measures

All participants completed a pre and post intervention questionnaire including closed and open-ended questions and clinical scenarios related to DUB. Variables examined included:

- awareness of recent evidence and practice guidelines in the investigation and management of DUB in women 40 years or less.
- perceived referral or booking rates for diagnostic hysteroscopy and/or dilatation and curettage in women 40 years or less with DUB
- attitudes and practices related to education and evidence based clinical practice

In addition participants were asked to nominate a person they considered to be an expert in this area of gynaecology ('opinion leader').

The number of hysteroscopies and/or dilatation and curettages performed on public patients was collected from ICD10 codes from the South Australian Health Commission database. Data, using ICD 9 codes, on the number of diagnostic hysteroscopies and/or dilatation and curettages performed for DUB each year on women 40 years or less for the past 6 years in each of the 6 hospitals was collected

to determine any trends and examine pre-intervention data. Post intervention data was collected from July 1999 to December 1999.

Data analysis

Behavioural outcome data was analysed using Excel and SPSS. Chi-squared and relevant non-parametric coefficients were calculated for all variables and confidence intervals provided where relevant. A type I error of $p=0.05$ was used. Comparisons were made between pre and post study procedure rates in the control and intervention arm.

Logistics

Ethics approval was granted from the Flinders Medical Centre Clinical Research Ethics Committee. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) approved 8 cognate points in the category of Planned Learning Project (PLP).

A reminder postcard was sent to all non-responders 3 weeks after first recruitment phase. Follow-up phone calls were undertaken with non-responding gynaecologists, as well as a second mail out of the information sheet, consent form and questionnaire.

Results

The response rate was 74.2% (46/62). Table 1. illustrates the participant characteristics. Responders were more likely to be younger and have fewer years of fellowship/training. See table 1. Following randomization, 3 hospitals were assigned each to the intervention and the control arm. The different numbers of participants in the 2 arms represent a greater pool of specialists in the control hospitals. Specialists in the intervention group had significantly more years of experience than those in the control. See table 2.

INSERT TABLE 1 and 2 ABOUT HERE

No consistent pattern was evident on the number of diagnostic hysteroscopies and/or dilatation and curettages performed for DUB on women 40 years or less from 1993-1998 in each of the 6 hospitals prior to the study. To determine whether the number of procedures had changed since implementation of the educational strategy, data from July – December 1998 was compared with the same time period in 1999. The educational strategy was not effective in reducing the number of hysteroscopies and D&Cs performed. See table 3.

INSERT TABLE 3 ABOUT HERE

However, the educational strategy resulted in more evidence based behaviour in the use of investigations for DUB when measured by performance in the follow up questionnaire which used clinical-based scenarios. See table 4 This change in behaviour toward the evidence based guidelines occurred despite 57 % of participants reporting that the risk of missing something and patient preference contrary to the guidelines may be barriers to changing practice. Only 28.5% reported medical legal considerations being a barrier.

INSERT TABLE 4 ABOUT HERE

Table 5 illustrates the lack of significant impact of the intervention on reported booking rates for procedures.

INSERT TABLE 5 ABOUT HERE

Discussion

Whilst the results demonstrate some effectiveness in changing specialist clinician behaviour, as measured by theoretical application of evidence based guidelines to case scenarios, it failed to demonstrate any real change in patient outcomes ie a reduction in the number of hysteroscopies and D&Cs performed. That is, behavioural change when around theoretical cases has not translated into actual practice change when measuring patient outcomes. The reliability of self reported activity as a measure of behaviour change has been questioned by others, in particular, overestimating compliance with recommendations.²⁸

Participants in this study identified a number of potential barriers to changing their clinical behaviour in line with the guidelines including fear of missing something and patient preference. Fear of missing something was addressed in part in the study by the use of an opinion leader who was a gynaecological oncologist whose clinical practice is directed to what clinicians fear missing – hyperplasia or cancer. As in the United States, defensive medical practice pervades our Australian practice and drives over investigation.²⁹ Ideally educational strategies should attempt to target these barriers to maximise their effect.³⁰ Whilst the interactive workshop allowed for some exploration of these issues, the use of role play and direct discussion of these issues may have improved the educational impact.

As with other surgical fields, a remuneration system particularly in the private arena “rewards” procedural interventions such as hysteroscopy /D&C. Both in the Australian public and private sector, the coding and attached financial payment for a surgical procedure as a day or overnight case attracts much greater payment to the hospital or specialist than performing a radiological investigation or screening a patient by history at a specialist consultation. Whilst the study was undertaken in public teaching hospitals and only outcomes on public patients considered, the majority of specialists in the study also provided private practice outside the public hospital setting. Clinical practices in private

practice are likely to inform a specialist's practice in the public setting. Whilst such procedures in these young women continue to attract a remuneration, other incentives to change practice may need to be considered.

Significant to this study and its applicability is the difference between responders and non responders. Gynaecologists who consent to participate in a study that involves being educated in current evidence based practice in a particular area are potentially different to the non responders. The responders were found to be younger and have less years of experience. That is, older, more experienced practitioners were less likely to agree to participate. Issues such as receptivity to change, time constraints and 'expert driven practice' may have contributed. This is important to consider when contemplating future research directed at behaviour change in this area.

An inquiry was made of potential confounding factors, in particular, change in service provision, that may have occurred at the control hospital units to explain the significant reduction in procedures performed during the study period. The rates of hysteroscopies/D&Cs were quite variable in the 3 control hospitals prior to the study period with no consistent trend. In one control hospital, due to budget overrun, gynaecological operating services were severely curtailed for 2-3 months of the post intervention study period. No change in service provision ie operating theatre closures, outpatient hysteroscopy clinic closure, reduced outpatient episodes were noted in the other 2 units. Unfortunately the chief investigator, whilst not a participant, was one of 18 staff providing clinical gynaecology services and supervision of trainees at one of the control hospital during the study period. There was therefore potential contamination in this one hospital. In addition, this hospital had been the only one to demonstrate a consistent fall in numbers of hysteroscopies and D&Cs for the 3 years preceeding the study, raising the issue of additional confounders in this institution. Further review of the clinical outcome data at 12 and 18 months post intervention is required.

Whilst no difference was found in respect to the intervention strategy, numbers of hysteroscopies and D&Cs in all units decreased during the study period and behavioural outcomes gave some support for

the usefulness of education and awareness raising. General educational activities such as College CME activities for Fellows and preparation courses and materials for membership for registrars are likely confounders, but in a positive direction.

Limitations of the study

Whilst no changes in patient outcomes were measured a number of factors could account for this finding. A larger study, such as Wyatt et al (1998) involving more hospital units over a larger region, may have been able to compensate for potential contamination factors.³¹ The second issue relates to the timing of collection of outcome data in the 6 month period following the educational intervention. No difference was found but the effect may not be apparent for 12 to 18 months. Others have suggested that awareness of, and knowledge of guidelines may peak at 12 months while actual change in practice may not be seen till after 2 years.^{28,32} Thirdly, contamination, as discussed above is difficult to prevent even with clustering especially in a small community of specialists. In addition, there are likely to be multiple factors operating as confounders in the promotion of new or changing clinical practice with potential greater impact than the strategies chosen in this study.

In the timetable of this study it was not possible to engage with the target audience with the guidelines, particularly in development and modification to local needs, prior to their introduction within the intervention. Ownership of guidelines has been identified as a key element to effecting behaviour change.^{20,21,33} However, results from this study showed high satisfaction with the educational material and perceived ability to adhere to the guidelines. Engaging 'experts' (specialists gynaecologists) in the development has the potential to 'water down' the evidence based guidelines in order to reach consensus. Many examples exist of guidelines in this area that are not strongly based in evidence.^{5,34} There may be a trade off with seeking optimal ownership by participants and maintaining guidelines strongly grounded in best evidence.

The choice of primary outcome for this study was made with the desire to measure the effectiveness of the intervention on the 'gold standard outcome'; patient health outcomes. This assumes that performing less unnecessary surgical investigations improves patient health. However, measurement of other outcomes such as uptake of alternative investigations such as ultrasound and patient satisfaction may have provided further information about the effectiveness of the intervention. Ideally, a longer follow up study could examine subsequent management outcomes such as the uptake of therapeutic interventions including medical management options and hysterectomy.

This study was limited to attempting to change to behaviour of specialists health care providers. Many recommend using several routes of influence to assist in clinical outcome change, in particular via education of consumers and internal and external health organisations.^{33,35}

Future research/Implications

Examining strategies to effect change in clinician behaviour toward the use of best evidence is still paramount. This is especially so when the change required involves stopping or reducing an unnecessary intervention, in this study, a diagnostic test.. This clinical problem can largely be managed by primary care practitioners, and behaviour change in this group of practitioners may maximise the impact on patient care. Whilst specialists and the hospitals continue to be remunerated for doing investigative procedures as opposed to more conservative evidence based management, a conflict to change in this area will persist.

Other strategies need to be developed by external players such as the government /Health Insurance Commission.²⁸ Consideration needs to be given to the removal of medicare/DRG remuneration for this procedure in young women without risk factors. Alternatively a change in hospital policy via unit director leadership may be another strategy. Education of consumers of the service has not yet been addressed. This audience could be explored further as a mechanism to change clinician behaviour.³⁵

Any future use of guidelines may be enhanced by validation of the guidelines by the local audience or respected body such as the NHMRC or RANZCOG. This requires sufficient lead up time for this to occur prior to the project.

CONCLUSIONS

Participants in an evidence based educational study identified practitioners not necessarily representative of the greater population of clinicians. Whilst the evidence based educational strategy for the appropriate investigation of young women was considered valid and able to be implemented by specialists and resulted in behaviour change when applied to theoretical cases, it did not result in changes to patient care. Changes in clinical outcomes may not be apparent till 1 to 2 years post intervention and should be re examined at these points. Potential barriers to behaviour change amongst clinicians have been identified. Strategies directed at other avenues in the health care management should be considered in the future to address this problem.

(3006 words)

Acknowledgements

This study was funded by NHMRC. The investigators wish to thank Dr. Margaret Davy for her support and expertise.

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Table 1 Participant characteristics

	Total number	Responders	Non Responders
No. of hospitals	6	6	0
No. of Practitioners	62*	46	16
Professional status:			
Registrar	29 (47%)	24 (52%)	5 (31.5%)
Staff Specialist	8 (13%)	7 (15.5%)	1 (6%)
Visiting Medical Officer	23 (37%)	14 (30.5%)	9 (56.5%)
Academic	2 (3%)	1 (2%)	1 (6%)
Gender:			
Male	42 (68%)	30 (65%)	12 (75%)
Female	20 (32%)	16 (35%)	4 (25%)

*68 practitioners originally approached, 6 of which were ineligible due to not completing 12 months duration of study at hospital

All NS

		median	range	median	range
Age (years)		37	24-64	51	27-60*
Years of fellowship/training (years)		4	1-25	15.5	1-20**

* Significant difference $z = -2.431$ $p = 0.015$

** Significant difference $z = -2.321$ $p = 0.019$

Table 2. Characteristics of study groups

	Control n = 28		Intervention n = 18	
	median	range	median	range
Age (years)	37.5 [↑]	28 - 60	35.5	24 - 64
Years of experience:				
Fellow	7	1 - 20	20	2 - 25*
Registrar	4	1 - 7	4	1 - 6
Clinical awareness score	1	0 - 3	1 [↑]	0 - 3
Perceived procedure rates (%)	25	8 - 100	30	10 - 75

[↑] Denotes missing cases: 2 and 1 respectively

* Significant difference: $z = -1.989$; $p = 0.047$ (Mann Whitney Test)

All other differences are NS

	Control n = 28	Intervention n = 18
Gender:		
Male	19 (68%)	11 (61%)
Female	9 (32%)	7 (39%)
Professional status:		
Consultant	15 (54%)	7 (39%)
Registrar	13 (46%)	11 (61%)

All differences are NS

Table 3 No. of hysteroscopies and D&Cs performed pre and post study

	No. of hysteroscopies/D&Cs (July – Dec 1998) pre-study	No. of hysteroscopies/D&Cs (July – Dec 1999) post study
Control	395	277*
Intervention	304	288**

* Significant $\chi^2 = 35.25$ df = 1 $\alpha = .05$ $p < 0.05$

** $\chi^2 = 0.84$ df = 1 $p > 0.05$

Table 4 Performance with clinical scenarios

	Awareness Score Pre -intervention		Awareness Score post - Intervention	
	median	range	median	range
Control (n = 28)	1	0 - 3	1	0 - 3*
Intervention (n = 16)↑	1	0 - 3	0	0 - 2**

↑ denotes 1 case missing

* Difference NS

** Significant difference: $z = -2.565$; $p = 0.012$ (Wilcoxon Signed Ranks Test)

Table 5. Reported booking rates for hysteroscopies and D&Cs

	Hysteroscopy/D&C booking rate per doctor pre-intervention		Hysteroscopy/D&C booking rate per doctor Post - intervention	
	median	range	median	range
Control (n = 27) ↑	25	8 - 100	25	10 - 85*
intervention (n = 15) ↑	30	10 - 75	25	7 – 75**

↑ denotes missing cases (1 and 2 respectively)

* Difference NS

** Difference NS – However direction of change desirable and $z = -1.940$; $p = 0.052$) (Wilcoxon)