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SHOULD WE PACK IT IN? A PROSPECTIVE RANDOMISED DOUBLE BLIND STUDY ASSESSING THE EFFECT OF VAGINAL PACKING IN VAGINAL SURGERY

Hypothesis / aims of study

Vaginal surgery has a low incidence of complications in the literature but recent evidence suggests a higher post-operative morbidity than previously believed. [1] Vaginal packs are commonly used following pelvic surgery to reduce post-operative complications although there are no data to support or refute this practice. Anecdotal evidence suggests that the pack is associated with post-operative pain which has led to debate regarding the value of vaginal packing.

The primary aim of this study was to examine the effect of vaginal packing on post operative pain. The secondary aims were to assess its effect on post-operative complication rates, specifically: post-operative haematological and infective morbidity; and post-operative pelvic haematoma formation.

Study design, materials and methods

This was a prospective, double blinded randomised study. Women were recruited from a tertiary referral urogynaecology unit between October 2008 and January 2010. All women over the age of 18 years, English literate and able to provide informed written consent who were admitted to undergo a vaginal hysterectomy and/or pelvic floor repair were invited to participate. Patients deemed to be at higher risk of post-operative morbidity i.e. clotting abnormalities, immunocompromised state or previous pelvic surgery were excluded. Patients were only withdrawn from the study if there were specific intra-operative concerns expressed by the surgeon.

Randomisation to receive a pack or not post operatively was carried out using a sealed envelope technique. Opaque non-resealable envelopes were utilised and sealed containing one of an equal number of labels 'Pack' or 'No Pack' at the beginning of the study. Envelopes were randomised and attached to the patients' notes. They were opened in theatre by the anaesthetist only at the end of the procedure.

The primary outcome was to compare day 1 post-operative pain between the two groups. This was assessed by researchers questioning the patients and completing the Short Form McGill Pain score.[2] The researcher and the patient were only informed regarding the group assignment after this. The secondary aim was to compare post-operative morbidity between the two groups. This was evaluated comparing haematological and microbiological investigations performed pre-operatively, and day 2 and 6 weeks post-operatively. Blood loss was assessed using changes in the haemoglobin (Hb) and platelet count(Plt). Post operative infectious morbidity was studied using changes in the white blood count (WBC) and cultures of high vaginal swabs (HVS) and mid-stream urine samples (MSU). A transvaginal ultrasound scan was performed at 6 weeks to exclude pelvic haematoma. Figure 1 illustrates the four main stages of the protocol.

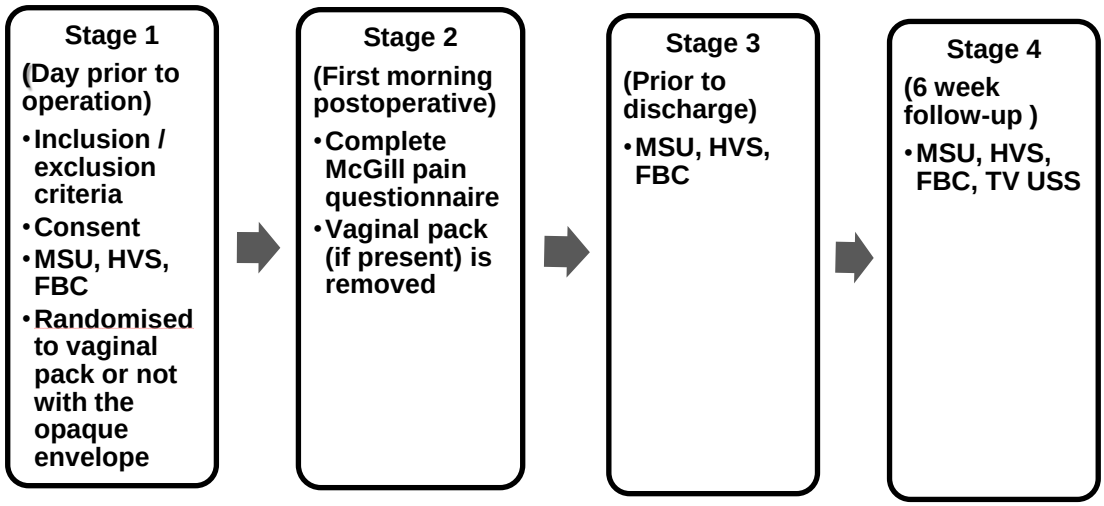

Figure 1: Study protocol

The study was powered using a two sides test to compare means of the two independent groups, and 86 women were required in each group to achieve 90% power at the 0.05 significance level. Statistical analysis was performed using SPSS (V 17, Chicago, Illinois) using an intention to treat analysis.

Results

In total 173 women were recruited with mean age 58.3 years (range: 27-91 yrs), mean BMI 27.4 (18-50) and mean parity 2.9 (0-12). 86 patients were randomised into the 'Pack' group and 87 into the 'No Pack' group. Due to intra-operative bleeding 5 patients from the 'No Pack' group were withdrawn and packed. There were no demographic differences between the groups. There was no statistically significant difference in the post-operative Short-form McGill pain scores or any of the secondary outcome measures**.[Table 1]** However there were 3 clinically significant complications in the 'No Pack' group whereas there were none in the 'Pack' group**.[Table 2]**

Outcome measure		Pack group	No pack group	Mean change p value
Pain		12.19	10.73	0.298
Haematological				
Hb mean	pre-op	12.95	12.91	
Day 1 post-op		11.75	11.94	0.061
6wk follow up		12.55	12.49	0.884
Plt mean	pre-op	315.51	295.28	
Day 1 post-op		269.08	286.24	0.483
6wk follow up		317.35	328.98	0.354
Hematoma		4	9	0.098
Infective				
WCC mean	Pre-op	7.50	8.40	
Day 1 post-op		10.24	11.34	0.318
6wk follow up		7.28	8.19	0.354
MSU change	Day 1 post-op	8	8	1.000
6wk follow up		20	16	0.575
HVS change	Day 1 post-op	10	10	1.000
6wk follow up		26	30	0.518

Table 1: **Results**

	Group allocation	Outcome
Patient 1	No Pack	Returned to theatre with bleeding from recovery
Patient 2	No Pack	Infected haematoma, admission for intravenous antibiotics
Patient 3	No Pack	Infected haematoma, admission for intravenous antibiotics

Table 2: Significant complications

Interpretation of results

This is the first prospective randomised double blind study to examine the effect of post-operative vaginal packing. There is no evidence to suggest that it increases pain scores or post-operative morbidity. Whilst the number of haematoma between groups was not significantly different, clinically there was a trend towards more significant complications in the 'No Pack' group. It is important to remember that this study was powered based on the primary outcome of pain and not haematoma formation, therefore it may be that this study lacked the power to detect this change. Our current data would support the use of vaginal packing in clinical practice although a larger multicentre RCT would provide more robust evidence.

Concluding message

Vaginal packing following pelvic reconstructive surgery does not lead to an increase in post-operative pain, infection or haematological morbidity and may reduce the risk of haematoma formation, therefore it should be recommended as routine practice.

References

1. What is the incidence of infection post vaginal surgery? The 34th annual meeting of the International Urogynecological Association, Villa Erba, Cernobbio, Italy - June 16-20, 2009.
2. McGill Short Pain Score. Pain. Vol 30(2) Aug 1987, 191-197.

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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**