Commercial Prolapse Repair "Kits" vs. Traditional Transvaginal Prolapse Repairs: A Comparison of Efficacy and Cost

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Abstract:
INTRODUCTION AND OBJECTIVES: To compare costs and short-term surgical outcomes following traditional transvaginal prolapse repair and commercial prolapse "kits." METHODS: We reviewed the records of 60 consecutive women who underwent transvaginal prolapse repair at 2 training institutions. Group 1 (N=30) underwent a traditional prolapse repair. Group 2 (N=30) underwent similar compartment repairs with the APOGEE™ or PERIGEE™ kits (AMS, Minnetonka, MN). All had a concomitant sling procedure. Patients were matched for compartment of prolapse using both Baden-Walker and POP-Q grading. Abstracted costs were: operating room (OR), disposable materials (DM), and room and board (RB). Statistical analysis was performed with Mann-Whitney and Chi-square tests, where applicable. RESULTS: Mean follow-up was longer for group 1 (20 vs. 15 months, $p<0.0001$) and minimum follow-up was 12 months for both groups. Age, parity, body mass index, and pads per day were similar for both groups. Women in group 1 had a significantly higher degree of preoperative anterior compartment prolapse (mean Point Ba: 1.6 vs. -0.01, $p=0.0232$) and apical compartment prolapse (mean Point C: 1.07 vs. -1.38, $p=0.001$). Rates of postoperative transfusion and short-term urinary retention were not statistically different (NS). Postoperative resolution of anterior and posterior compartment prolapse was effective for both groups (NS); however, a significantly higher % of women in group 2 developed asymptomatic apical prolapse (32% vs. 7%, $p=0.016$). Two patients in each group required additional surgery for symptomatic prolapse RB costs were significantly higher for group 1 {\$1017 (95% CI: \$800-\$1234) vs. \$732 (95% CI: \$643-\$821), $p=0.037$}. OR time and cost were similar (NS). For group 2, DM cost {\$2412 (95% CI: \$2360-\$2465) vs. \$790 (95% CI: \$658-\$922), $p<0.0001$) and total cost {\$5743 (95% CI: \$5563-\$5923) vs. \$4558 (95% CI: \$4267-\$4848), $p<0.0001$} were significantly higher. Controlling for cost of sling materials and operative time did not significantly alter the cost profiles.
CONCLUSIONS: Currently, disposable materials account for the significant cost difference between the 2 types of repairs. During short-term follow-up, both repairs provide excellent support for the anterior and posterior compartment. There were a significant number of patients in group 2 that developed asymptomatic apical prolapse. Longer follow-up is needed to see if these patients eventually become symptomatic and require further surgery, which may contribute to a further difference in long-term costs.

Introduction

Traditional transvaginal Pelvic Organ Prolapse (POP) repair is associated with low morbidity and rapid recovery but has variable rates of recurrence, that may approach 40% in some cases.[1 2] Interposition with allografts, xenografts and synthetics may decrease recurrence, but there are few head-to-head outcome comparisons vs. traditional repair. [3 4] More recently, commercial prolapse "kits" have become more commonly used. They propose to combine interposition grafting with smaller incisions, limited dissection, shorter operative time, and less postoperative pain. A downside to these procedures may be the significant cost of disposable materials. While initial results have been encouraging, long-term outcomes of "kit" repairs have not yet matured, and results have not been compared to traditional POP repairs. The goal of this study was to compare the short-term efficacy and cost of traditional POP repair versus "kit" repairs.

Materials and Methods

Following IRB approval, a retrospective data analysis was done from two training institutions – Summa Health Systems, Akron, OH and Louisiana State University, Shreveport, LA. Data on 60 consecutive women undergoing prolapse repair were examined. The 60 women were divided into 2 groups. Group 1 (n = 30) consisted of 30 women who underwent anterior colporrhaphy, posterior colporrhaphy, enterocele ligation, vault suspension (iliococcygeus or sacrospinous). Group 2 (n = 30) consisted of women undergoing a "kit" prolapse repair with either the APOGEE or PERIGEE prolapse repair system (AMS).

For each patient, we analyzed patient demographics (see figure 1), POP-Q and Baden-Walker prolapse grade, and costs, complications, and need for additional repairs. Statistical analysis was done using Mann-Whitney test.

Operating room costs were calculated at $22/minute and room and board was $610/day. Disposable material for the Apogee and Perigee were $1395 and $1500 respectively. The other disposable costs are shown in figure 2.

Figure 1: Patient Demographics

	Group 1	Group 2	P
N	30	30	
Age	62.8	64.7	0.4290
Race	97% Caucasian	90% Caucasian	0.6574
BMI	27.3	27.9	0.6224
Gravity	3.08	3.48	0.3899
Parity	2.92	2.93	0.9929

Figure 2: Disposable Material Costs

Monarc Sling	$995
Pelvicol	$595
Bovine	$400
Capio (Device)	$250
Interposition Pelvicol Mesh	$790
Bovine Interposition Mesh	$525
Prolene Interposition Mesh	$300
Apogee Kit	$1395
Perigee Kit	$1500

Results

POP-Q grading for prolapse was evaluated pre and post operatively. Analysis of pre-op Pop-Q revealed that women in group 1 had a significantly higher degree of preoperative anterior compartment prolapse (mean Point Ba: 1.6 vs. -0.01, p=0.0232) and apical compartment prolapse (mean Point C: 1.07 vs. -1.38, p=0.001). All other POP-Q indices were not significantly different in the two groups. (see figure 3)

Figure 3: Post Operative Results

POP-Q	**Group 1**	**Group 2**	**P**
Aa	-2.73	-2.75	0.9342
Ba	-2.80	-2.78	0.6539
Ap	-2.77	-2.45	0.5815
Bp	-2.80	-2.50	0.6003
C	-5.57	-4.58	0.1188
TVL	8.82	8.72	0.7660
GH	4.13	4.12	0.7872

Mean follow-up was slightly longer in Group 1 but this was not statistically significant. (19.8 vs. 14.7 months ($p<0.0001$); Minimum follow-up for all women was 12 months. For both Groups, POP-Q points Aa, Ba, Ap, Bp, and C were significantly improved when compared to preoperative indices. There was no significant change in total vaginal length or genital hiatus.

There was no significant difference in pre and post POP-Q points for either group except when evaluating asymptomatic apical prolapse. (defined as $C \geq -4$cm):
Two women in group 1 (7%) and 9 women in group 2 (32%) had asymptomatic apical prolapse. p=0.0157

Postoperative complications were not significantly different between the two groups. The most common complication was post-operative urinary retention which was experienced by 4 patients in each group. (see figure 4)

Two patients in each group required additional procedures during the follow-up period. In group 1, one patient underwent abdominal sacral colpopexy and another underwent posterior repair. In group 2, two patients underwent abdominal sacral colpopexy.

Figure 4: Postoperatiave complications

Complication	**Group 1**	**Group 2**
AUR < 1 month	2	2
AUR > 1 month	2	2
Cystotomy	1	0
Post Vaginal Wound Dehiscence	2	0
Transfusion	1	0
Vaginal Cuff Bleed ((-) Takeback)	0	1
Suprapubic Cellulitis	1	0
Atrial Fibrillation	2	0
Congestive Heart Failure	1	0

Figure 5 shows a breakdown of the cost analysis. Operating room time was not significantly different between the two groups. (125 minutes vs. 118 minutes). The primary difference in cost between the groups resulted from disposables with Group 1 averaging $790 and Group 2 averaging $2412. While length of stay trended to be longer for the traditional prolapse repair group, this was not statistically significant. The total cost difference was $5743 for Group 2 vs. $4558 for Group 1. (p<.0001).

Figure 5: Costs

	Group 1	**Group 2**	**P**
OR Time (min) (95% CI)	125 (117-133)	118 (110-125)	0.2032
OR Cost (95% CI)	$2751 ($2580-2923)	$2599 ($2428-2770)	0.2032
Disposables (95% CI)	$790 ($658-922)	$2412 ($2360-2465)	<0.0001
R&B (95% CI)	$1017 ($800-1234)	$732 ($643-841)	0.0371
Length of Stay (days)	1.62	1.17	0.0679
Total (95% CI)	$4558 ($4267-4848)	$5743 ($5563-5923)	<0.0001

Discussion

Traditional transvaginal POP repairs rely on plication of a woman's existing "fascia," obliteration of potential space, and attachment of the vaginal apex to fixed pelvic landmarks. While this approach is typically associated with low perioperative morbidity, recurrence rates may be high due to inherent weakness of the woman's tissues. For this reason, interposition-graft repairs of the anterior and posterior compartment may decrease recurrence of prolapse. Results of randomized studies to verify this belief are infrequent and difficult to interpret.[5] The difficulty in interpretation stems from several reasons including, variable duration of follow-up, and variable definitions of cure and recurrence. Furthermore, the graft itself (i.e. synthetic, xenograft) may be associated with unique complications and sequelae. The majority of published articles are retrospective in nature with no standardized inclusion criteria or outcomes evaluation. Moreover, unlike urogenital malignancies which are followed on a regular basis, patients with successful prolapse repairs are often not followed for several years after surgery unless problems develop.

Commercially-available prolapse "kits" have marked the continued evolution in the treatment of POP. Owing to their novelty, most reports of outcomes are in abstract form with only short term follow-up data. Tunn and colleagues reported on 120 patients undergoing either Apogee or Perigee repair with 1 year follow-up.[6]
They report excellent short term results with a 93% success rate with only 7% of women still having residual prolapse

Thus far comparative studies have not been published. We do know that "kits" may be associated with substantial additive costs and this was found to be the case in our small retrospective series. One of the proposed benefits of "kit" surgery is the need for less dissection and presumably decreasing operative room time. While our series did not find this to be the case, we do anticipate that after the initial learning curve, operative time may very well decrease as number of cases increases.

The long-term impact of mesh implantation in young women is not yet known. There have been high rates of dyspareunia reported in the literature, but we have not found this to be the case in our study population.[7,8] Another long term concern is mesh erosion. With increasing use of estrogen creams post-operatively many believe this will continue to remain a minor risk.[9]

Conclusions

During short-term follow-up, both traditional repairs and "kit" repairs are associated with excellent anterior and posterior compartment support, a brief hospital stay and few perioperative complications. We found that "kit" repairs may be associated with

asymptomatic apical prolapse. Longer follow-up will determine if these women eventually require additional surgery to repair these defects. "kit" surgery is significantly more expensive at this time, mainly due to increased cost of disposables. This difference persists after controlling for OR time and cost of a sling.
At this time, OR time was not significantly shorter with the "kit" procedures. This may be explained by the learning curve of a novel procedure performed in the setting of training institutions. With increased experience, shorter OR times may be realized for the "kit" procedures, potentially narrowing the gap in cost between "kits" and traditional repairs.

Figure 6: Operative Procedures

Repair	**Group 1**	**Group 2**
Vaginal Hysterectomy	7	8
Anterior Repair (with Graft)	22 (4)	8
Posterior Repair (with Graft)	23 (2)	8
Enterocele Ligation	19	5
Iliococcygeus Hitch	12	0
Sacrospinous Ligament Fixation	18	0
APOGEE	0	16
PERIGEE	0	14
Sling Procedure (various)	30	30
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APOGEE	0	16
PERIGEE	0	14
Sling Procedure (various)	30	30

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