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Obstetric balloon as a pelvic spacer to mitigate the risk of empty pelvis syndrome in patients undergoing total pelvic exenteration for rectal cancer

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Title

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IRB approval number: 4938

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Patient consent was not required because this was a retrospective audit of routinely collected clinical data. All patient information was anonymised, and patient confidentiality was maintained throughout the study.

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Abstract

Aim: Empty pelvis syndrome (EPS) causes substantial morbidity after total pelvic exenteration. We evaluated whether an obstetric (Bakri) balloon used as a pelvic spacer reduced EPS after exenteration for rectal cancer.

Method: This single-centre retrospective study included adults undergoing total pelvic exenteration between October 2013 and December 2025. Patients undergoing bladder-sparing, posterior or supralevator exenteration were excluded. The Bakri balloon became unit protocol in December 2019. The primary outcome was EPS, defined by pelvic collection, bowel descent causing obstruction, perineal hernia, enteroperineal fistula or delayed urinary leak. Factors associated with EPS were assessed using multivariable logistic regression.

Results: Overall, 211 patients were included; 186 (88.2%) were men and median age was 46 years. A Bakri balloon was used in 115 patients (54.5%). EPS occurred in 46 patients (21.8%): 22 (47.8%) presented within 30 days and 24 (52.2%) thereafter. Pelvic collections were the

commonest manifestation (45.7%), followed by acute bowel obstruction (21.7%), enteroperineal fistula (15.2%), delayed bowel obstruction (8.7%) and delayed urinary leak (8.7%). Radiological and surgical interventions were required in 25 and 21 patients, respectively. Bakri balloon placement did not significantly reduce EPS (OR 0.71, 95% CI 0.37–1.37; P=0.305). Minimally invasive surgery was independently associated with lower EPS risk (adjusted OR 0.39, 95% CI 0.19–0.80; P=0.011).

Conclusion: EPS remains a significant early and late complication after total pelvic exenteration. Temporary Bakri balloon placement did not provide sustained protection against EPS.

Obstetric balloon as a pelvic spacer to mitigate the risk of empty pelvis syndrome in patients undergoing total pelvic exenteration for rectal cancer

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Introduction

Pelvic exenterations are the only curative modality in rectal adenocarcinoma with persistent contiguous organ infiltration after neo-adjuvant therapy[1]. These procedures carry with them, significant short and long term morbidity, including an impact on body image and the psychological footprint of living with two ostomies. Despite advances in peri-operative care and improvements in long term support, questions regarding complications arising in the remnant pelvic cavity remain unanswered. The void resulting from the removal of all pelvic viscera gives rise to an often under-reported yet clinically significant complication called empty pelvis syndrome (EPS). With the rise in the number of radical exenterations performed for pelvic malignancies, an academic interest in delineating the components of this complication has gained momentum. The incidence of empty pelvis syndrome has been reported to be up to 40% in available literature[2]. The PelvEx group defines EPS as the herniation, descent, or prolapse of small bowel loops and mesentery into the pelvic cavity following major pelvic resections, leading to mechanical, infectious, or vascular complications due to the loss of pelvic floor support and obliteration of normal anatomic barriers[3]. The clinical presentation of empty pelvis syndrome is multifaceted, ranging from pelvic collections to entero-perineal fistulae and bowel obstruction. While the management of these complications has been standardised over time, there has been very little progress in preventing them.

The prevention of empty pelvis syndrome has two core strategies: filling up the hollow space after resection and prevention of bowel descent by blocking the pelvic inlet. While several methods have been proposed to prevent EPS, attempts to identify a clear winner have failed[2]. We have previously reported the use of an obstetric balloon (Bakri balloon) as a pelvic spacer to prevent empty pelvis syndrome in patients undergoing exenteration[4]. The short term results were promising, showing a decrease in the incidence of EPS, as well as lower requirement for surgical intervention[5], we now report long term results in a larger cohort of patients.

We aim to shed new light on the efficacy of the Bakri balloon in mitigating the risk of empty pelvis syndrome in patients undergoing total pelvic exenteration for rectal carcinoma.

Additionally we will be reporting the gamut of presenting symptoms and the association between Bakri balloon and the need for a surgical or radiological interventions.

Methods

Study design, setting & patient population

This is a retrospective observational study conducted from a single tertiary care centre in India. Patients aged 18-75 yrs undergoing total pelvic exenteration between October 2013 to December 2025 were included in the analysis. The use of the Bakri balloon to fill up the pelvic cavity commenced in December 2019, and was the unit protocol since then. A minimum follow up of 30 days was required to document the occurrence of empty pelvis syndrome. Complications arising within 30 days were classified as early EPS, while those occurring after wards were classified as late EPS. Patients undergoing bladder sparing exenterations, posterior exenterations and supra-levator exenterations were excluded from the study.

Obliteration of the pelvic cavity

Following the delivery of the specimen from the perineum and achieving hemostasis, the pelvic cavity was irrigated with normal saline. Depending on the size of the perineal defect, a unilateral or bilateral V-Y myo-cutaneous flap was raised for closure. Depending on the size of the perineal defect, involvement of the plastic surgery team was sought. No other myo-cutaneous flaps were used to bridge the defect. A Bakri balloon along with a flat drain were introduced into the pelvic cavity and the balloon was inflated with upto 500ml of normal saline till the cavity is obliterated. The position of the balloon at the pelvic inlet was confirmed and all bowel loops were placed above the level of the pelvic inlet, with the urinary conduit being the lower-most loop in the abdominal cavity. The urinary conduit was fixed to the retro-peritoneum and the right lateral abdominal wall to prevent any internal herniation.

Gradual deflation of the Bakri balloon was done from post-operative day seven, by aspirating 50-100ml of saline per day. Once empty, the Bakri balloon was removed from the pelvic cavity followed by the removal of the flat drain two days later.

Variables & Outcomes

The primary outcome of interest in this study was the incidence of empty pelvis syndrome in patients undergoing total pelvic exenteration. The various presenting symptoms in affected patients were included in the analysis. These included:

1. Collections in the pelvic cavity detected on follow up imaging or requiring drainage or resulting in discharge from the perineal wounds.
2. Descent of small bowel loops into the pelvic cavity causing symptoms of subacute intestinal obstruction or obstipation.
3. Perineal hernias.
4. Perineal entero-cutaneous fistulae.
5. Delayed urinary leaks (occurring >30 days after the index surgery)

Interventions needed for the above complications were classified into image guided intervention and surgical exploration. Complications were graded using the Clavien-Dindo classification.

Statistics

Data was recorded and analysed using the SPSS version 26 software. Continuous variables were reported as medians. Categorical variables were reported in proportions and compared

using the Fischer's chi-square test. Non parametric comparisons were made using the Mann–Whitney U-test.

In order to assess the impact of the various factors affecting outcomes related to empty pelvis syndrome, binary logistic regression was performed, keeping empty pelvis syndrome as the dependant variable.

Possible confounding factors associated with empty pelvis syndrome, such as sex, BMI, pre-operative radiation, the use of Bakri balloon and surgical approach (open vs minimally invasive), bone resections, pelvic node dissections were analysed. Backward stepwise logistic regression was used and factors retaining a p-value of <0.1 were included in the final result. Odds ratios were reported with 95% confidence interval.

Results

Details regarding the baseline clinico-pathological data are provided in table 1. The median age of our cohort was forty six years and 88.2% of the patients were male. Majority of the patients had a primary tumour in the low/mid rectum with only twelve percent of the tumours in the recto-sigmoid/sigmoid region. Poorly differentiated adenocarcinoma accounted for about 40% of the cases. The median BMI of our cohort was 21.6kg/m2 with 26.5% of the patients having a high BMI (>/=25kg/m2)

Neo-adjuvant treatment & details of the surgical approach are outlined in table 2. Pre-operative radiation was given to 93.4% of the patients (59.2% LCRT vs 24.2% SCRT); whereas, 64.9% of the patients received neo-adjuvant chemotherapy. Of the two hundred and eleven exenterations performed during the study period, 52% of the cases were operated via the open approach whereas laparoscopic and robotic resections were performed in 41.2% and 6.2% respectively. Pelvic lymph node dissection was performed in 55.9% of the cases, whereas 12.8% of the cases underwent sacrectomies to ensure an R0 resection. The workhorse for perineal reconstruction in our unit has been the V-Y myo-cutaneous flap. We didn't use the V-RAM or gracilis flaps for perineal reconstruction in any of our patients.

The Bakri balloon was used a pelvic spacer in 115 patients (54.5%) (Figure 1). Empty pelvis syndrome was noted in 21.8% of the patients(n=46) in our cohort (table 3). The most common presentation was a collection in the pelvis (45.65%), detected on follow up imaging or presenting with perineal discharge. Acute (<30 days) and delayed (>30 days) bowel obstruction accounted for 21.7% and 8.6% of EPS respectively, while 15.21% patients presented with an entero-perineal fistula. Delayed urinary leak (>30 days post-op) was noted in 8.6% of the patients usually from the proximal end of the ileal conduit stuck to the pelvic brim (Figure 2). There was no difference in the timing of EPS (<30 days vs >30 days)(p=0.562) or occurrence of different manifestations between both the groups (p=0.315) (table 4)

Image guided drainage or surgical interventions for empty pelvis syndrome were required in 21 and 15 patients respectively. Of the patients requiring a surgical intervention, 50% had a Bakri balloon placed in the pelvis, compared to 16.6% who did not have a Bakri balloon placed before closure (p=0.16). Bowel obstruction (acute or delayed) and entero-perineal fistulae were the most common indications for a surgical exploration.

The impact of various factors contributing to the incidence of EPS, such as placing the Bakri balloon, pre-op radiation, MIS vs open surgery, reconstruction by plastic surgeon, BMI and sex was studied using binary logistic regression. On univariate analysis, MIS approach was the only predictive factor (OR=0.373,CI=0.183-0.762; p=0.007). Similar trend was noted in the

multivariate regression analysis as well, MIS (OR=0.39, CI=-.188-0.804; p=0.011) and BMI (OR=0.93, CI=0.865-1.005; p=0.067). Placement of the Bakri balloon did not significantly impact the incidence of EPS in our cohort (table 5).

Discussion

Our study evaluated the role of the Bakri balloon as a pelvic spacer to mitigate the risk of empty pelvis syndrome in patients undergoing total pelvic exenteration for locally advanced rectal cancer. The incidence of EPS in our cohort was 21.8%. Across available literature, the incidence of EPS ranges from 10-40% due to varying definitions and inconsistent reporting[2,3,6]. Utilising the contemporary definition by PelvEx group given in 2025, our incidence falls within the reported range, highlighting that EPS is a common cause of morbidity following exenterations.

EPS is a spectrum of symptoms ranging from collections, fistulae, bowel herniation and obstruction to pelvic sepsis. In our cohort, pelvic collections needing drainage was the most common manifestation, similar to the findings of the PelvEx core data set[6].

The strategies to prevent empty pelvis syndrome has two major components: filling the pelvic cavity and preventing bowel descent into the pelvis. The Bakri balloon was placed into the before perineal closure and removed in the following two weeks, giving enough time for the bowel to adhere in the supra-pelvic compartment. While the balloon addressed the first component of the problem, prevention of bowel descent still persisted. Since EPS is a time dependent complication, short term results appeared promising, making the balloon placement our unit policy. However, with a larger cohort and longer follow up, the effect of the Bakri balloon to prevent EPS was not sustainable. Also, empty pelvis syndrome is a multifactorial problem, with previous radiation, radicality of surgery, sex, BMI, bone resection, pelvic lymph node dissection, size & shape of the pelvic cavity and the approach to surgery contributing to its occurrence. Hence, a temporary spacer in the pelvis may be insufficient in preventing the complication from occurring months following resection.

Several factors including the radicality of surgery, pre-op EBRT dose, acute post op inflammation may influence empty pelvis syndrome. The PelvEx core data noted increasing rate of EPS with increasing dose of radiation at 1% per 1Gy of radiation. Additionally, performing high sacrectomy (above S2), major nerve resection, internal iliac artery ligation, major bony resection, also may contribute to EPS[6]. We have not reported these findings due to the limited numbers in our series.

Minimally invasive approach was the only factor predictive for EPS with a protective effect. Similar findings have been reported in a meta-analysis by Ryan et al[7]. In their study, MIS was associated with lower rates of pelvic abscess or sepsis. The mechanism behind this observation may be associated with reduced post operative inflammation and decreased tissue handling during minimally invasive surgery. The persistent effect on univariate and multivariate regression analysis suggests that the operative approach might influence the development of empty pelvis syndrome. While the risk of selection bias cannot be ruled out, since the intention was to introduce confounders to Bakri balloon rather than surgical approach, it is very much possible that the observation can be a part of table 2 fallacy.

Notably, we used only local V-Y advancement flaps for perineal reconstruction. The negative findings of the Bakri balloon is not evidence against pelvic reconstruction. It only highlights the limitation of a temporary spacer. Studies showing V-RAM flaps, placement of the omentum,

breast prosthesis and even cecum to obliterate the pelvic space have all failed to show a reduction in the incidence of EPS[8-15]. Evidence supporting various mitigation strategies for EPS is derived mainly from retrospective studies and is of low level. While positive results were reported by our group and also with the use of the biosynthetic mesh, the PelvEx group[6] did not reach any consensus for the use of prosthetic devices. However, there was consensus regarding the utilisation of autologous tissue such as omentoplasty, myo-cutaneous flaps or other structures. The probable reason for hesitation regarding the use of prosthetic devices stems from the problem of associated inflammation, leading to bowel migration and adhesions with the passage of time. Carboni et al[11] reported perineal wound SSI and bowel leaks in 7.1% in their cohort. They had no bowel obstructions or entero-perineal fistulae, and the prosthesis was left in the pelvis in majority of the cases. Authors from Romania presented a case report of a patient having entero-perineal fistula after exenteration with an un-resectable pelvic recurrence. Following resection and anastomosis of the involved loop, the authors placed 3 foley's catheters in the pelvis for 6 weeks in order to prevent subsequent bowel migration[17]. A systematic review of reconstruction techniques for EPS and randomised controlled trials have shown that mesh reconstruction[18] and breast implants[11,13] had less bowel obstructions, perineal hernias or perineal fistulae. Similar findings were found in the patients with myo-cutaneous flaps. Silicone expanders were also effective in keeping the bowel out of the pelvis albeit with a high rate pelvic collections in the long run[19]. The use of the obstetric balloon was associated with the highest rates of perineal wound dehiscence and small bowel obstruction[2].

Current methods used for preventing EPS are suboptimal. While synthetic meshes are easily available and cheap, their propensity to cause an inflammatory response leads to adhesions. The use of autologous tissue solves this problem, however long term results are not sustained and pelvic floor weakness may not be addressed. We attempted to reduce the duration for which the Bakri balloon is placed, removing it in a week, however the effect of this strategy remains to be seen. The use of tissue engineered repair materials (TERM), primarily used for pelvic floor dysfunction patients may offer hope for the future[20]. It uses a combination of materials, cell lines, drugs and growth factors. The material component provides mechanical support and a physical barrier, additionally it acts like a niche for delivering the cell components, drugs and growth factors. The cell lines and growth factors in turn allow for tissue remodelling to improve pelvic floor strength.

The use of human acellular dermal matrix with a muscle flap[21] and porcine dermal acellular collagen (in place of human derived matrices)[22] effectively provided a barrier between the abdominal viscera and the neo-pelvis, thereby preventing empty pelvis syndrome. However, evidence supporting them is currently limited.

Strengths & Limitations

To the best of our knowledge, our study represents one of the largest single centre cohort evaluating the use of a temporary spacer for preventing empty pelvis syndrome following total pelvic exenteration. The large cohort and extended follow up period allowed us to study the evolution and manifestations of EPS. Our centre is a high volume tertiary referral centre for exenterations and all resections were done using a standardised approach. Outcomes of our study have been reported using the definitions provided by the PelvEx group.

However, certain limitations must be addressed. The main limitation of our study is its retrospective nature. The placement of the Bakri balloon commenced in 2019 and the use of a

historical control introduces a selection bias. Additionally, the improvement of patient selection operative techniques and perioperative care over time may have influenced outcomes. Our unit used only local V-Y flaps for perineal reconstruction. V-RAM and gracilis flaps were not. While a multivariate analysis was performed to account for potential confounders, the effect of residual confounding cannot be eliminated. Lastly, this is a single centre experience and generalisability of the results is not possible. A prospective multi-centre effort applying various intra-op and peri-operative measures is needed to answer this issue.

Conclusion

Empty pelvis syndrome is a clinically significant complication in patients undergoing total pelvic exenteration. Its evolution of over time and multifaceted manifestations make it a difficult problem with limited answers. While the use of the Bakri balloon as a pelvic spacer showed promise during our initial experience. The long term results are not sustainable.

Table 1. Baseline Demographic and Tumour Characteristics

Characteristic	Value
Age	
Mean ± SD	45.4 ± 13.1
Median (range)	46 (17–79)
Sex	
Male	186 (88.2%)
Female	25 (11.8%)
BMI	
Mean ± SD	21.9 ± 4.4
Median (range)	21.6 (13.9–57.0)
Tumor differentiation	

Well/Moderately differentiated	120 (58.5%)
Poorly differentiated	85 (41.5%)
Tumor site	
Rectum	197 (94.3%)
Rectosigmoid/Sigmoid	12 (5.7%)

Table 2. Neo-adjuvant Treatment and Operative Characteristics

Characteristic	n (%)
Neoadjuvant treatment	
Any neoadjuvant therapy	196 (94.2)
Preoperative chemotherapy	137 (65.9)
Neoadjuvant chemoradiotherapy	125 (60.1)
Short-course radiotherapy	51 (24.6)
Surgical approach	
Open	110 (52.4)
Laparoscopic	87 (41.4)
Robotic	13 (6.2)
Lateral pelvic lymph node dissection	

Yes	118 (56.5)
No	91 (43.5)
Sacrectomy	
Yes	27 (12.9)
No	182 (87.1)
Perineal reconstruction	
V-Y myocutaneous flap	211 (100.0)
VRAM flap	0 (0.0)
Gracilis flap	0 (0.0)

Table 3. Empty Pelvis Syndrome: Incidence, Manifestations and Management

Characteristic	n (%)
Incidence	
EPS	46 (21.8)
No EPS	165 (78.2)
Time to presentation (n=46)	
Early (<30 days)	22 (47.8)
Late (≥30 days)	24 (52.2)

Clinical manifestations (n=46)	
Pelvic collections	21 (45.7)
Acute bowel obstruction	10 (21.7)
Enteroperineal fistula	7 (15.2)
Delayed bowel obstruction	4 (8.7)
Delayed urinary leak	4 (8.7)
Management	
Radiological intervention	25 (11.8)
Surgical intervention	21 (10.0)
Bakri balloon placement	115 (54.5)

Table 4. Distribution of Empty Pelvis Syndrome (EPS) Manifestations According to Bakri Balloon Placement

EPS manifestation	Bakri balloon (n=115)	No Bakri balloon (n=96)	P-value
Pelvic collections	10 (8.4%)	11 (11.4%)	
Acute bowel obstruction	5 (4.2%)	5 (5.2%)	
Delayed bowel obstruction	2 (1.7%)	2 (2.1%)	

Enteroperineal fistula	3 (2.5%)	4 (4.1%)	
Delayed urinary leak	2 (1.7%)	2 (0.2%)	
No EPS	93 (80.8%)	72 (75%)	
Overall comparison			0.948

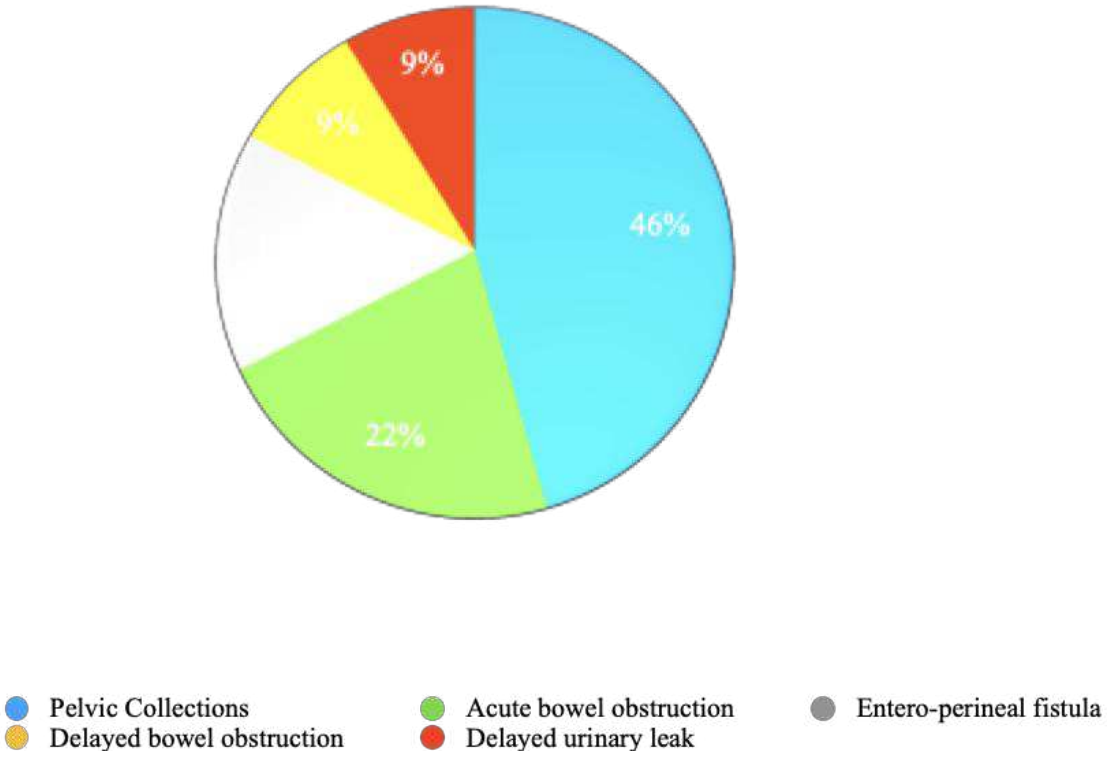
Factor	Univariate OR (95% CI)	P	Multivariable OR (95% CI)	P
Minimally invasive surgery	0.373 (0.183–0.762)	**0.007**	0.389 (0.188–0.804)	**0.011**
Bakri balloon	0.710 (0.369–1.367)	0.305	—	NS
Preoperative radiotherapy	0.853 (0.370–1.964)	0.708	—	NS
Plastic reconstruction	0.544 (0.280–1.059)	0.073	—	NS
BMI	0.939 (0.873–1.010)	0.092	0.934 (0.869–1.005)	0.067
Male sex	0.868 (0.325–2.317)	0.777	—	Excluded

Table 5. Univariate and Multivariable Logistic Regression Analysis for EPS

Figure 1:A) Intra-op picture of Bakri balloon placed in the pelvis prior to closure of the perineal defect; B) Axial image of follow-up CT scan showing pelvic collection with bowel loops in the pelvic cavity; C) Sagittal image of follow up CT scan of the same patient.



Figure 2: Clinical manifestations of EPS (n=46)



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