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Open prostatectomy with a rectal balloon: A new technique to control postoperative blood loss

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ABBREVIATIONS

RB, rectal balloon;
TVP, transvesical prostatectomy;
PVR, postvoid residual urine volume;
Q_{max}, maximum urinary flow rate

Abstract ***Objectives:*** To evaluate a new technique, the rectal balloon (RB), to control blood loss after transvesical prostatectomy (TVP).

Patients and methods: Over 2 years 100 patients were prospectively randomised into two equal groups. All patients underwent TVP for their benign prostatic hyperplasia but a RB (a balloon fixed to a three-way Foley catheter tip by a plaster strip, making it airtight) was used in group 2. The RB was placed in the rectum opposing the prostate and inflated (pressure controlled) for 15 min. Haemoglobin levels were assessed before and after TVP. Blood transfusion, the amount of saline used for irrigation, duration of catheterisation, hospital stay, and rectal complaints were recorded. Patients were followed up at 1 and 3 months after TVP.

Results: The enucleated adenoma weight was 102 g in group 1 and 106 g in group 2. There was a significant difference between groups 1 and 2 in haemoglobin loss within the first 24 h after TVP, and in total loss, of 0.9 g and 0.2 g ($P = 0.008$), and 1.9 g and 1 g ($P = 0.001$), respectively. There was also a significant difference between the groups in the saline volume used for irrigation (11.4 vs. 2.5 L), catheter duration (5.7 vs. 4.3 days), and hospital stay (6.2 vs. 5.1 days), favouring group 2.

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Blood transfusions were needed in four patients in group 1 and one in group 2. There were no rectal complaints.

Conclusion: The use of an inflated RB after TVP is a simple and safe procedure with no specific operative technique, that reduces postoperative blood loss, the incidence of blood transfusion, the volume of saline for irrigation, and shortens the catheterisation period and hospital stay, with no rectal complications.

Introduction

Open prostatectomy, either retropubic or transvesical, is the oldest and most invasive management for BPH [1]. It has been replaced by TURP in many countries, and currently represents ≈3% of all prostatectomies in the USA, and 12–32% in Europe, reaching up to 40% in some developed countries, where laser technology is not available [2,3].

New techniques are available for open surgery on prostates of > 100 g, such as holmium laser enucleation of the prostate, or a laparoscopic approach, with good results and less comorbidity than open prostatectomy, but they require lengthy training, with greater costs and more equipment [3].

Peri-operative bleeding is one of the major complications of open prostatectomy. The incidence of blood transfusion due to bleeding is 2–36%, and sometimes as high as 50% [2,3].

In 1951 Hryntschack described separation of the bladder neck from the prostatic fossa to control postoperative bleeding. De La Pena used a removable purse-string suture, and Malment used removable partition sutures (cited in [4–6]). Lezrek et al. [7] used a removable partition purse-string suture at the bladder neck, and the prostatic fossa was drained.

Other techniques are capsular plication either longitudinal or transverse, packing the prostatic fossa with gauze or by an inflated catheter balloon, early vascular control before cystotomy, and transurethral endoscopic coagulation by a second surgical team [8,9]. Kirollos [10] reported that life-threatening bleeding after prostatectomy (the patient received 12 units of blood) was controlled only by anterior digital rectal pressure for 10 min. Thereafter, Osman et al. [11] used a gauze pack inserted into the patient's rectum opposing the prostate, after TVP. Kilciler et al. [12] used a rectal Foley catheter to decrease rectal bleeding after TRUS-guided prostate biopsy, although it was not possible to measure the pressure inside it.

In the present study, at the end of TVP, we used an inflated rectal balloon (RB) and evaluated its efficacy in controlling postoperative blood loss, and the feasibility and adverse effects compared to a control group without a RB.

Patients and methods

From October 2010 to March 2013, 100 patients were prospectively randomised into two equal groups, using randomising software (random.org), so that every even number was allocated into group 1 and every odd number into group 2. All patients underwent TVP performed by senior staff, and a RB was used only in group 2.

Patients included presented with LUTS that was not responding to medical treatment, or with refractory or chronic urinary retention due to their BPH. Prostate volume (mass) was measured using TRUS and was > 80 g. A TRUS biopsy was taken to exclude malignancy when indicated. Informed consent was obtained from each patient to join the protocol. The ethics committee of the Faculty of Medicine, Fayoum University, approved the protocol.

Patients were excluded if they had a prostate volume of < 80 g by TRUS, prostate cancer, bladder tumour, neurogenic bladder, abnormal bleeding profile, anorectal pathology or previous anal surgery.

Before TVP each patient was assessed for surgical and anaesthetic fitness. All patients had history taken (and completed the IPSS), a clinical examination (with DRE), laboratory values (PSA) and radiological investigations (TRUS, abdomino-pelvic US with an assessment of the post void residual urine volume, PVR). The maximum urinary flow rate (Q_{max}), mean flow rate and voided volume were obtained by uroflowmetry. On the day of surgery the patients had a rectal enema, and before surgery a blood sample was taken to measure the haemoglobin level. All patients had a diagnostic cysto-urethroscopy under regional anaesthesia, and then TVP (using the Freyer technique) [1].

In group 2 the RB was inserted before TVP into the rectum, above the anal sphincter and opposing the prostate. The RB was prepared by inserting the tip of a three-way Foley catheter into a medium-sized balloon (5 × 7 cm) and then fixed by a plaster strip, making it airtight (Fig. 1A and B). The small channel of the catheter was attached to the pump of the sphygmomanometer for air inflation (inside the balloon), and the large channel attached to the mercury storage of the sphygmomanometer to measure the pressure during inflation

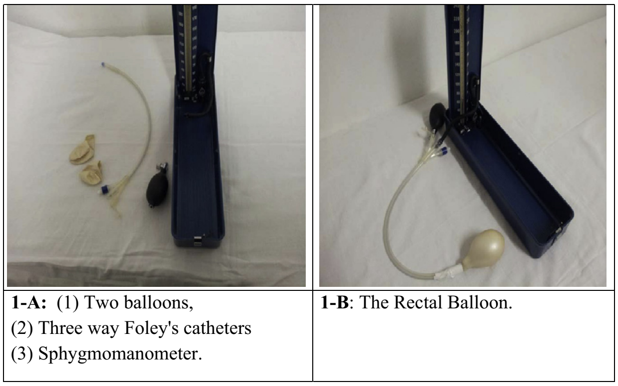

Figure 1 The composition of the RB. (A) Two balloons, the three-way Foley catheter and the sphygmomanometer. (B) The RB assembled.

of the balloon inside the rectum. The position of the RB is shown in Fig. 2.

After adenectomy the haemostatic techniques were the same in all patients. The prostatic fossa was packed with gauze for 5 min. Two haemostatic sutures were made at the 5 and 7 o'clock positions, with separate sutures or cauterisation by diathermy for other bleeding sites. A Foley catheter (20 F) balloon was inserted in the prostate bed and inflated to a volume less than the infravesical part of the enucleated adenoma, to avoid interfering with the retractile power of the prostatic capsule [1].

In group 2, after adenectomy, the RB was inflated to a pressure between the systolic and diastolic pressure of the patient for 15 min (the normal clotting and bleeding time is <15 min), and thereafter deflated and removed from the rectum. Meanwhile, the anal sphincter was inspected for any abnormalities. No patient developed bleeding after the deflation of the balloon.

Suprapubic and urethral catheters for irrigation were inserted, then the bladder made watertight and bladder irrigation started as a slow drip. A retropubic tube drain was fixed and the wound closed anatomically. A blood sample was then taken to estimate the haemoglobin level, from which the amount of blood lost during surgery was estimated. The patient was then discharged to the ward. A typical patient undergoing TVP with a RB is shown in Fig. 3.

The operative duration was calculated and the haemoglobin level determined 24 h after surgery. When the bladder wash became clear it was stopped. The amount of saline used for irrigation was calculated for each patient. At three days after TVP another blood sample was taken to determine the total haemoglobin loss. The suprapubic catheter was removed after stopping irrigation, and the urethral catheter was removed 3–5 days later. Finally the tube drain was removed. After a successful trial of voiding the patient was discharged. The catheter duration and length of hospital stay were recorded for each patient. Regular follow-up visits were scheduled at 1 and 3 months and patients were followed-up using the IPSS, PVR, Q_{max}, mean flow rate, voided volume and any rectal complaints.

The results were analysed statistically using Student's *t*-test, the chi-squared test and Fisher's exact test, as appropriate, to compare results between the groups, with $P < 0.05$ considered to indicate statistical significance.

Results

Of the 100 patients included, 33 (33%) presented in urinary retention and 15 had a bladder stone, with no significant difference between the groups. The baseline characteristics of all patients are shown in Table 1, with no statistically significant differences between them.

The mean (SD, range) enucleated adenoma weight was 102 (39.6, 65–238) g in group 1 and 106 (44, 66–228) g in group 2, and the respective operative duration was 65 (14, 50–105) min and 71 (11, 55–112) min, with no significant differences between the groups.

Before inflation of the RB the mean (SD) haemoglobin loss was 0.83 (0.37) g/dL in group 1 and 0.72 (0.29) g/dL in group 2, with no significant difference between the groups. The mean haemoglobin loss within the first 24 h after TVP is shown in Table 1, and there was a significant statistical difference between the groups ($P = 0.008$). There was also a significant

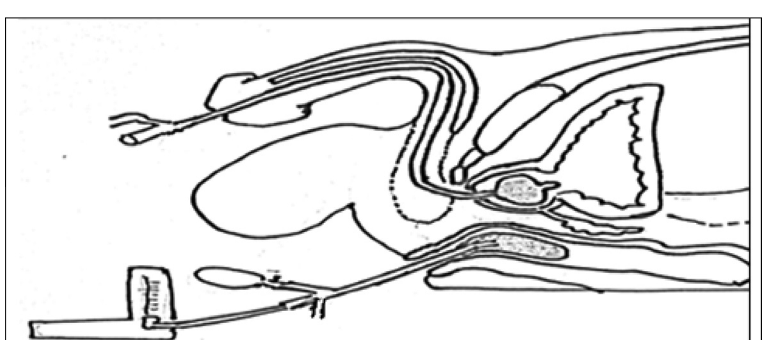

Figure 2 A diagram showing the position of RB.

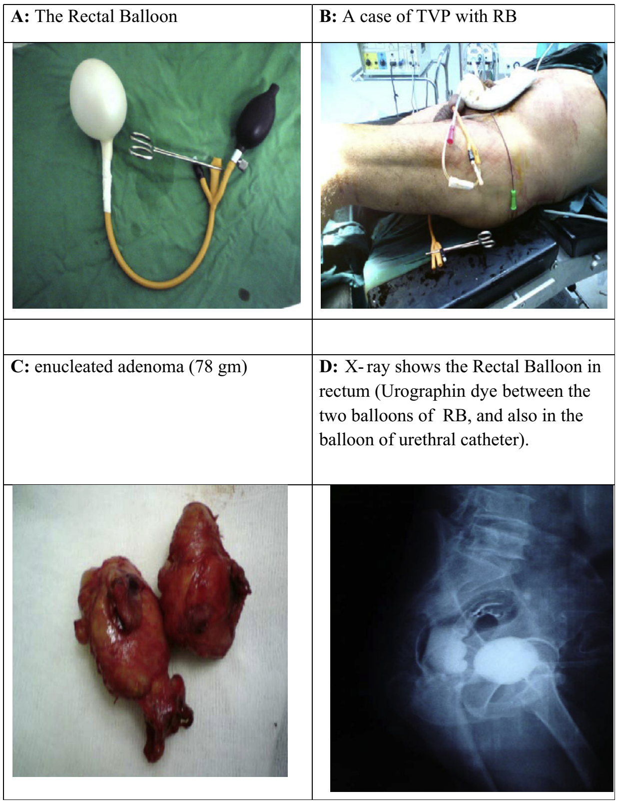

Figure 3 (A) The RB assembled ready for use. (B) A patient undergoing TVP with the RB in situ. (C) An enucleated adenoma (78 g). (D) A radiograph showing the balloon in the rectum (with contrast medium between the two balloons of the RB, and in the balloon of the urethral catheter).

difference in the total haemoglobin loss (peri-operative), with less loss in group 2 (1.9 g vs. 1 g; Table 1). A blood transfusion was needed in four patients in group 1, vs. only one in group 2. No patient had clot retention or a re-operation due to bleeding after TVP.

There were significant statistical differences between the groups in the volume of saline used for bladder irrigation, catheter duration, and hospital stay, in favour of group 2. (Table 1).

Two patients developed a seroma and wound infection in each group, and all were treated by frequent wound dressing. Also, two patients had a UTI in group 1 and one in group 2, all treated by appropriate antibiotics.

The follow-up after 3 months (IPSS, Q_{max} and PVR) showed a statistically significant improvement over baseline in both groups, with no significant difference between them (Table 1). Two patients in group 1 and one in group 2 had urinary incontinence after TVP, and this resolved in all within the first month of the follow-up period. No patient had any rectal complaint, such as rectal bleeding, tenesmus, and anal pain, nor stool incontinence. None of the pathology reports showed malignancy.

Discussion

In countries with a deficient healthcare system, patients with BPH/LUTS often delay presentation, even when they have a poor response to medical treatment, so such

Table 1 The baseline characteristics, changes in haemoglobin, operative values, and the efficacy of TVP in the two groups.

Mean (SD, range)		Group 1	Group 2	*P*
Age (years)		65.6 (4.1, 58–74)	66.5 (4.5, 57–75)	0.34
IPSS		24 (3.6, 20–32)	23.5 (3.7, 20–31)	0.49
Urinary flow rate, mL/s				
Mean		3.7 (2.1, 0–6)	3.6 (1.9, 0–6.2)	0.59
Q_{max}		6.8 (3.8, 0–10.9)	6.6 (3.3, 0–11)	0.90
Haemoglobin (g/dL)		13.6 (1.1, 11.4–15.4)	12.9 (0.9, 11.8–14.6)	0.45
Prostate volume (mL)*		121.8 (43.3, 81–270)	125.1 (48.6, 82–255)	0.73
PVR (mL)		214 (217, 75–780)	195 (210, 70–750)	0.69
Changes in haemoglobin level (g/dL)				
Loss during TVP		0.83 (0.37, 0.5–1.9)	0.72 (0.29, 0.5–1.8)	0.42
Loss within 1st 24 h		0.94 (0.31, 0.5–1.4)	0.23 (0.12, 0.1–0.5)	0.008
Loss to 1 day after TVP		1.77 (0.56, 1–3.2)	0.95 (0.38, 0.6–2.3)	0.001
Total loss (3 days)		1.96 (0.41, 1.3–3.3)	1 (0.32, 0.8–2.4)	0.003
Saline (L)		11.5 (2.8, 7–18)	2.5 (0.5, 1.7–3.5)	0.009
Catheter duration (days)		5.7 (0.7, 5–9)	4.3 (0.4, 4–5.5)	0.002
Hospital stay (days)		6.2 (1, 5.5–10)	5.1 (0.4, 4.5–6)	0.003
Efficacy of TVP				
PVR (mL)	Before	214 (217)	195 (210)	0.001
	After	8 (4)	10 (3)	
IPSS	Before	24 (3.6)	23.5 (3.7)	0.003
	After	2 (1)	2 (1)	
Q_{max} (mL/s)	Before	6.8 (3.8)	6.6 (3.3)	0.001
	After	26 (3)	25 (3)	

* By TRUS.

countries have many patients with a large prostate (>80 g). Open TVP is a rapid, less costly and definitive treatment for BPH in developing nations. Bleeding (during and after surgery) remains a serious complication of open prostatectomy, despite great efforts to manage this problem [2,3].

The idea of compressing blood vessels to stop bleeding by using pressure-controlled balloons was previously applied in the Sengstaken–Blakemore tube used for managing oesophageal-varices bleeding [13].

We combined the idea of a pressure-controlled balloon used in the Sengstaken tube, and the pressure applied on the prostate blood supply from the rectum, described by Kirollos [10] and modified by Osman et al. [11]. We then developed our new technique (RB), with a measured pressure in the rectum to avoid pressure necrosis on the rectal wall, to facilitate haemostasis.

In the present study, 33 patients (33%) presented in urinary retention, which is higher than reported in North America (10%) [3], and other studies [14,15], of 31%, and the Sicilian-Calabrian Society of Urology (23%) [2], but less than reported by John et al. [6] (69%). The mean (SD) IPSS for both the present groups was 23.2 (3) and 22.7 (3), higher than reported by Gratzke et al. [3] (20.7) and Evren et al. [15] (21.7). The mean (SD) $Q_{\max}$ of groups 1 and 2 in the present study was 7.3 (3.5) and 7.2 (3.3) mL/s, respectively, and less than reported by Gratzke et al. [3] (10.5) and Evren et al. [15] (9.3), but equal to that reported by Varkarakis et al. [5] of 7.3 (1.7) mL/s. This might be due to the delayed presentation in developing countries. The mean (SD) PVR in the present groups was 214 (217) and 195 (210) mL, respectively, both less than reported by others [3,5,15], at 145, 116 and 116 mL, respectively, as many patients were adapted to chronic retention with no obvious complaints.

There was a significant difference between the present groups in total prostate volume (Table 1) and the values were similar to that reported by Elshal et al. [14] (123 g), but larger than reported by others, e.g., [3] (96 g), [16] (114 g), [5] (104 g), [15] (98 g), [17] (96 g) and [2] (75 g). The mean (SD) weight of the enucleated adenoma was 102 (39.6) g in group 1 and 104 (42) g in group 2, comparable with values reported by Elshal et al. [14], but greater than reported by others, e.g., [4] (61 g), [16] (82 g), [3] (84 g), [17] (73.5 g) and [8] (89.9 g). There is agreement that there has been an increase in prostate weight since the advent of medical treatments, and prostates are larger in countries with inefficient healthcare systems, where patients present late.

The mean operative duration in group 2 (71 min) was longer than in group 1 (65 min), but was not significantly different, but the 6-min difference was the mean time needed for RB insertion and inflation. The operative duration was less than reported by others, e.g., [16] (101 min), and [3] (81 min), although the adenomas in those studies were smaller than in the present study, and we are more familiar with TVP.

To date there is no consensus on the ideal technique to control blood loss during TVP, so we used the same techniques for haemostasis in all patients (a pack in the fossa, two sutures at the 5 and 7 o'clock positions, coagulation of other bleeding sites, and placing a Foley catheter balloon in the fossa), but using the new technique (RB) in group 2. We measured the haemoglobin loss throughout TVP and afterwards. The mean loss during TVP was similar in both groups (≈0.8 g/dL) and was comparable to that reported by Condie et al. [6] (0.8 g/dL, within the first day), although they did TVP with a removable bladder neck partition suture, with its hazards.

The loss within the first 24 h after TVP and total loss were 0.94 and 1.9 g/dL for group 1, while in group 2 it was 0.23 g/dL and 1 g/dL, respectively, with a statistically significant difference between the groups. This represents the compression effect of the RB on the blood supply to the prostate from the rectum posteriorly, leading to a dramatic effect on bleeding control.

In TVP, after packing the fossa, and the two haemostatic sutures and suturing or cauterising other bleeding, the main blood loss is venous. Thus the pressure applied from both balloons decreases the blood loss. Although the total haemoglobin loss in group 2 was significantly less than in group 1, the total loss in group 1 was less than reported by others, i.e., [18] (3.5 g/dL in their control group), [14], 2.7 g/dL (the enucleated adenoma weight was comparable), [19], 2.8 g/dL, and [17], 1.3 g/dL (reporting only loss on the day of surgery), as the different techniques we used during TVP for blood control gave good results.

In Millen's technique, where the prostatic bed is directly exposed, we expect better bleeding control [6]. The haemoglobin loss in group 2 (1 g/dL) was less than reported by Shaeen and Quinlan [9] and Varkarakis et al. [18], where they used the Millen method with early vascular control (2.8 and 2.1 g/dL, respectively), although the enucleated adenomas in both studies were smaller (92 and 98 g) than in the present study. These differences represent the compression effect of the RB, which reduces the blood loss.

Our threshold haemoglobin level for blood transfusion is 10 g/dL. Four patients (8%) needed a blood transfusion in group 1, but only one (2%) in group 2, whereas the main loss was during surgery. However, there was no significant difference between the groups. Evren et al. [15] reported a relationship between the size of the prostate and the transfusion rate, so that with a prostate of $<100\ \text{cm}^3$ the transfusion rate was 9.4% but if $>100\ \text{cm}^3$ it was 19.2%. Other reported transfusion rates are 0–56.7% [6,14,18].

The transfusion rate in group 2 was in the lower range but in group 1 it was similar to those reported in large contemporary series, e.g., 12.7% [15] and 9.6% [18], and the prostate volume was 98 g in [15]. Oranusi et al. [19] reported that 2.8% of their patients needed a blood transfusion during surgery because of bleeding, and 18% did so after surgery.

There was a statistically significant difference between the present groups in the volume of saline used for bladder irrigation, favouring group 2 (Table 1), and this is attributed to a lower blood loss in group 2. The volume of irrigation in group was similar to that reported in [5] before those authors introduced the modified bladder neck repair (12 L), but they did not use irrigation after they used their technique. The volume of irrigant in group 2 was more than reported by Lezrek et al. [7] by 2.5 L, although they used the modified Denis technique, with its complications. As we report a new technique we were reluctant to use no irrigation, but the promising results could encourage the omission of irrigation after TVP.

Although the mean prostate volume in the present study was large (> 100 g), no patient has clot retention or a re-operation for bleeding, as we use many techniques for blood control, and with good results. Gratzke et al. [3] reported a 3.7% surgical revision rate due to bleeding. Also the present incidence of seroma formation and wound complications (4%) was comparable to those reported by Varkarakis et al. [5] (4.3%), and Meier et al. [4] (2.9%).

The duration of catheterisation in groups 1 and 2 was significantly different (Table 1), but that in group 2 was less than many studies [2,4,5,14,20], of 5, 5, 7, 7.9, and 8 days, respectively. The hospital stay in group 2 was significantly less than in group 1, and less than reported elsewhere [2–5,14,20], at 7, 6, 8.1, 9, 11.9 and 10 days, respectively, although the enucleated adenomas in the present study were larger than those reported in these studies [2–5,20].

There was a significant improvement in IPSS, Q_{max} and PVR for both groups (Table 1) as reported by others [2–4,6], with no significant difference between the groups. Notably, RB did not affect the quality of the improvement, but only the postoperative blood loss.

The present patients were treated in a University hospital, where there is no charge for the services, but the costs are lower in group 2 (e.g., less irrigant use, nursing care and hospital stay). Moreover, RB is a cost-effective technique that greatly reduces the blood transfusion rate, saline use, catheter duration and hospital stay. Further multi-centre widely based studies are recommended to confirm our findings and to document the outcome of a primary trial.

In conclusion, in developed countries the open prostatectomy remains an important option for managing large prostates, and so the skills required should be well-practised. Using a RB after TVP is a simple and safe procedure with no specific operative technique, and that reduces the postoperative blood loss, decreases the transfusion rate and use of saline for irrigation, shortens the catheterisation period and hospital stay, and causes no rectal complications. These promising results with the RB during TVP suggest that multicentre studies should be done to confirm the findings, and that it can be used in a Millen's prostatectomy.

Conflict of interest

None.

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