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Parastomal hernia after ileal conduit urinary diversion: re-visiting the predictors radiologically and according to patient-reported outcome measures

Ahmed M. Harraz (D), Ahmed Elkarta, Mohamed H. Zahran (D), Amr A. Elsawy (D), Mohamed A. Elbaset (D), Ali Elsorougy, Yasser Osman, Ahmed Mosbah, Hassan Abol-Enein and Atallah A. Shaaban

Urology and Nephrology Center, Mansoura University, Mansoura, Egypt

ABSTRACT

Purpose: To evaluate the predictors of post-ileal conduit (IC) parastomal hernia (PSH) based on a standard grading methodology and according to the patients reported outcome measures (PROM). **Methods:** A prospective evaluation for patients with IC attending their scheduled follow-up was conducted between December 2013 and October 2015. The hernia stage was determined according to the European Hernia Society (EHS) classification as types I and II included defect size \leq 5 cm without and with a concomitant incisional hernia, respectively. Types III and IV included defect size > 5 cm without and with a concomitant incisional hernia (high-grade hernia). The evaluation was performed by a non-contrast CT scan. PROM were defined as symptomatic if there were hernia-related abdominal discomfort, appliance problems, and/or bowel complications. Perioperative parameters were modeled for prediction of high-grade and PROM outcomes.

Results: PSH was diagnosed in 138 (39.9%) patients, symptomatic in 119 (34.4%) and high-grade in 59 (17%). Independent predictors of radiologically diagnosed PSH were hypoalbuminemia (odds ratio [OR]: 1.7; 95% Confidence interval [CI]: 1.1–2.7; p = 0.02), localised disease (OR: 0.6; 95% CI: 0.3–0.9; p = 0.04) and negative lymphadenopathy (OR: 0.4; 95%CI: 0.2–0.8; p = 0.004). Predictors of symptomatic PSH were hypoalbuminemia (OR: 2; 95%CI: 1.2–2.3: p = 0.003) and previous hernia surgery (OR: 2.1; 95%CI: 1.1–4.2; p = 0.024).

Conclusions: Only a small proportion of patients with PSH were asymptomatic. Preoperative hypoalbuminemia was the most significant factor contributing to the development and symptomatizing of PSH. Previous hernia surgery further contributed to the patient complaint.

List of abbreviations: (IC): Ileal conduit; (PSH): Parastomal hernia; (EHS): European Hernia Society; (PROM): Patient-reported outcome measures

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KEYWORDS Radical cystectomy; ileal conduit; parastomal hernia

Introduction

Ileal conduit (IC) and orthotopic bladder substitution are the most popular types of urinary diversion after radical cystectomy [1,2]. Parastomal hernia (PSH) is a devastating complication with a cumulative incidence reaching up to 50% at 2 years after surgery [3,4]. Repair of PSH could be accomplished *via* the open or minimally invasive approaches with mesh hernioplasty is the mainstay of treatment [5–8].

In recently published articles, the definition of PSH was based on non-contrast computerized tomography (CT) imaging and was defined as a protrusion of any abdominal contents through a defect in the abdominal wall created for IC [3,9]. Despite this definition is the academic definition of hernia; it does not reflect the clinical significance of PSH e.g. poorly fitting ostomy appliance, and/or abdominal disfigurement, patient discomfort, or the presence of complications. On the other hand, the appropriate definition or classification of PSH should mention the most practicable criteria and should be reproducible and ideal for comparison across studies. Therefore, the European Hernia Society (EHS) has published a classification of PSH taking into account the presence of an incisional hernia, their aim was to improve the ability to compare results of different studies and clinically grade the PSH [10].

Although the magnitude of the problem is significant, very few articles have examined risk factors of PSH after IC and methods of prevention [3,9]. Previous reports have used only the radiological evidence of hernia regardless of the grade or the patient-reported outcome measures (PROM). In this study, we classified the PSH based on the EHS classification and studied the incidence and predictors of high-grade hernia. In addition, analyses were repeated based on PROM.

Methods

Study design

A prospective cohort study for patients attending the outpatient clinic for follow-up after radical cystectomy and IC was conducted. The institutional review board has approved the protocol of the current study. Eligibility included all patients who underwent IC urinary diversion and attended

CONTACT Ahmed M. Harraz a ahmed.harraz@hotmail.com, harraza@mans.edu.eg 🗗 Urology and Nephrology Center, Mansoura University, Mansoura, Egypt © 2020 Acta Chirurgica Scandinavica Society

their regular follow-up visits between December 2013 and October 2015. Exclusion criteria included patients with evidence of disease recurrence or missed follow-up. Patients who underwent repair of PSH were evaluated at the last visit prior to repair.

Measurements

Perioperative data were retrieved from a prospectively maintained electronic database and included patient age, gender, associated comorbidities, and body mass index (BMI). Obesity was defined as BMI > 30. From the laboratory investigations, serum albumin level was retrieved and hypoalbuminemia was defined as serum albumin level less than 3.5g/ dL. Perioperative complications were graded based on the modified Dindo-Clavien system [11]. Wound dehiscence was defined as wound complications that required intervention under spinal/general anesthesia. Histopathological cell type as well as tumor (pT) and lymph node (pN) staging were documented.

Patients were questioned specifically for symptoms of increased intra-abdominal pressure e.g. cough, constipation, or chronic straining as well as smoking history. Chronic smokers were considered if patients had smoked > 20 years [12]. Patients were carefully examined for the presence of PSH, other abdominal wall hernias, or the presence of any associated stomal problems. The examination was performed in both the supine and erect position and using the Valsalva maneuver. All patients underwent a single non-contrast computerized tomography scan (CT) and the images were revised and reported by a single dedicated radiologist.

Surgical technique and follow-up

None of our patients received neoadjuvant chemotherapy. We adopt a standard technique for fashioning an IC after radical cystectomy. A stoma therapist examines the patient to determine and marks the appropriate site of stoma prior to surgery. After radical cystectomy, 15 cm of the terminal ileum is isolated and restoration of intestinal continuity is obtained. The predetermined stoma site is incised and minimal subcutaneous fat is dissected till the rectus sheath is approached. A cruciate incision is then performed at the anterior rectus fascia and the rectus muscle is split and a similar cruciate incision is performed in the opposing posterior fascia and peritoneum. The aperture should admit at least the tips of two fingers. However, a wider or narrower opening might be required based on the surgeon's preference. The conduit is then passed through the opening and fixed to both the anterior rectus sheath and posterior fascia/peritoneum with 2-0 polyglactin sutures all around sparing the cranial part to avoid compression of the vascular mesentery. The stoma is then reflected upon itself using 3-0 poliglecaprone sutures. Ureters are then anastomosed to the proximal end of the IC in an end-to-side fashion. A 16F Foley's catheter is then fixed for 5 days in the IC and ureteral stents for one week. During the abdominal wall closure, the posterior rectus sheath was sutured till the level of linea semilunaris and then the lower parts of both rectus abdominis muscles are approximated. Patients are then discharged for scheduled visits for oncological and functional outcomes lifelong.

Study outcomes

The primary outcome was to identify the predictors of the development of PSH based on EHS grade classification [10] and PROM. The proposed classification was based on the defect size and not the size of the sac. Types I and II included defect size \leq 5 cm without and with a concomitant incisional hernia, respectively. Types III and IV included defect size > 5 cm without and with a concomitant incisional hernia (Figure 1). We considered stages I, II as low grade and III, and IV as high grade. PROM were classified as symptomatic or asymptomatic. Symptomatic patients were those with either abdominal pain or discomfort, those with appliance problems (poor fit or leakage), and/or the presence of bowel symptoms (diarrhea or constipation). Time-to-event analysis was performed to investigate the relationship between the follow-up duration and the cumulative incidence of radiological, high-grade, and symptomatic PSH.

Statistical analysis

Categorical variables were compared using the chi-square test. Multivariate logistic regression was performed to determine independent predictors of PSH occurrence, high-grade (III-IV), and symptomatic PSH. The cumulative incidence of the outcomes was presented using the Kaplan Meier curve. Statistical analysis was performed using IBM version 20 statistical software and R programming language version 3.6.3 with *survival* and *survminer* packages. A *p*-value < 0.05 was considered significant.

Results

A total of 346 patients attended their scheduled follow-up visits during the specified period and were evaluated according to the predetermined protocol. The median (IQR) followup was 77 (38-118) months. CT scan identified 138 (39.9%) patients with radiological evidence of PSH. The majority of PSH was grade I in 59 (42.8%) patients, while grades II, III, and IV occurred in 20 (14.5%), 44 (31.9%), and 15 (10.9%) patients, respectively. The mean ± SD defect size in cm was 5 ± 1.6 cm while the mean \pm SD maximal length of the sac was 11 ± 4.4 cm and the maximal width was 5 ± 1.2 cm. On diagnosis, a conservative approach, using an abdominal binder, was adopted in 28 (20.3%) patients as they were asymptomatic and well-functioning. In another 28 (20.3%) patients, the intervention was denied. In 60 (43.5%) patients the procedure was not performed because of the presence of co-morbidities. The repair was scheduled in 22 (15.9%) patients among which 14 (10.1%) patients underwent hernioplasty. Table 1 demonstrates the characteristics of patients with PSH at the time of evaluation. The cumulative impact of the time elapsed since radical cystectomy is demonstrated in Figure 2. The cumulative incidence was gradually increasing



Figure 1. The European Hernia society grading of parastomal hernia: I: defect ≤ 5 cm with no associated incisional hernia. II: defect ≤ 5 cm associated with incisional hernia. III: Defect > 5 cm with no incisional hernia. IV: defect > 5 cm associated with incisional hernia.

 Table 1. Characteristics of patients with radiologically diagnosed parastomal hernia after ileal conduit urinary diversion.

Variable	No. (%)
Clinically detected hernia	
Supine	104 (75.4)
Erect	11 (8)
With valsalva	23 (16.7)
Co-existing hernias	
No	108 (78.3)
Incisional	10 (7.2)
Inguinal	18 (13)
Umbilical	1 (0.7)
Inguinal and incisional	1 (0.7)
PROM	
Asymptomatic	33 (23.9)
Abdominal pain (discomfort)	40 (29)
Appliance (poor fit, leakage)	40 (29)
Bowl symptoms	25 (18.1)
PPOM: Patients reported outcome measures	

PROM: Patients reported outcome measures.

until approximately 100 months when it showed a less steep rise thereafter.

Predictors of PSH

Table 2 shows the univariate analysis for factors associated with the presence of PSH on CT scans. The incidence of PSH was significantly associated with lower albumin level (45.8% vs 32.5%; p = 0.02), pathologically confirmed organ confined disease (46.4% vs 32.3%; p = 0.009) and negative lymph nodes (44.9% vs 23.7%; p = 0.001). On multivariate analysis, independent predictors of PSH occurrence included albumin < 3.5g/dL (odds ratio [OR]: 1.7; 95%Confidence interval [CI]:

1.1–2.7; p = 0.02), organ confined disease (OR: 0.6; 95%CI: 0.3–0.9; p = 0.04) and negative lymphadenopathy (OR: 0.4; 95%CI: 0.2–0.8; p = 0.004).

High-grade and symptomatic PSH

Patients with negative lymphadenopathy and chronic smokers were significantly associated with high-grade PSH (Table 3). Nevertheless, on multivariate analysis, only negative lymphadenopathy was an independent predictor (OR: 0.3; 95%CI: 0.2–0.6; p = 0.001) while smoking history did not maintain its significance.

Patients with clinically significant PSH were one and half times more likely to present with hypoalbuminemia at the time of surgery (p = 0.001) and had a previous history of abdominal hernia surgery (p = 0.01). Details of univariate analysis are demonstrated in Table 4. On multivariate analysis, both factors retained their significance (hypoalbuminemia: OR: 2; 95%CI: 1.2–2.3: p = 0.003; previous hernia surgery: OR: 2.1; 95%CI: 1.1–4.2; p = 0.024).

Discussion

Parastomal hernia is not an uncommon consequence following IC [13]. Most of the previous reports focused on the incidence and risk factors of developing PSH; nevertheless, the major drawback was that the different definitions of PSH were not consistent; for instance, clinical evaluation was used in some reports [5,13–15], while others used an image-



Figure 2. The cumulative incidence with the 95% confidence interval of radiologically diagnosed parastomal hernia (PSH), high-grade PSH based on the European Hernia Society (EHS), and symptomatic PSH.

Table 2. Univariate analysis for	factors predicting radiologically-defined	parastomal hernia after ileal conduit urinary diversion.
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Variable	Level	No hernia (<i>n</i> = 208)	Hernia (<i>n</i> = 138)	<i>p</i> -Value
Gender	Male	165 (61.1)	105 (38.9)	
	Female	43 (56.6)	33 (43.4)	0.4
Chronic smokers	No	139 (62.1)	85 (37.9)	
	Yes	69 (56.6)	53 (43.4)	0.3
Obesity (BMI $>$ 30)	No	142 (60.2)	94 (39.8)	
	Yes	66 (60.0)	44 (40.0)	0.9
Hypoalbuminemia	No	104 (67.5)	50 (32.5)	
	Yes	104 (54.2)	88 (45.8)	0.01
Coexisting hernia	No	198 (59.6)	134 (40.4)	
5	Yes	10 (71.4)	4 (28.6)	0.3
Previous hernia	No	189 (61.8)	117 (38.2)	
	Yes	19 (47.5)	21 (52.5)	0.08
Cell type	UC	141 (61.0)	90 (39.0)	
	SCC	50 (63.3)	29 (36.7)	
	Adenocarcinoma	8 (47.1)	9 (52.9)	
	Others	9 (47.4)	10 (52.6)	0.4
pT stage	Organ confined	89 (53.6)	77 (46.4)	
1 5	Extra-vesical	111 (67.7)	53 (32.3)	0.009
pN stage	Negative	140 (55.1)	114 (44.9)	
1 3	Positive	58 (76.3)	18 (23.7)	0.001
Postoperative complications*	No	179 (59.9)	120 (40.1)	
	Yes	29 (61.7)	18 (38.3)	0.8
Wound dehiscence	No	186 (59.4)	127 (40.6)	
	Yes	22 (66.7)	11 (33.3)	0.5

BMI: Body mass index; UC: Urothelial carcinoma; SCC: Squamous cell carcinoma.

Hypoalbuminemia: serum albumin < 3.5 g/dL.

*Postoperative complications were graded according to the modified Clavien system.

pT and pN stages were not available in 16 patients.

based definition [3,9]. In a recent systematic review, the authors found that there was no standardized methodology for reporting. In addition, most of the studies were dependent on retrospectively reviewed data, and imaging was done primarily for detecting local recurrence or other complications [16]. In our study, we adopted the EHS classification [10] which is a validated tool that can be used for comparison between different centers. In addition, the relationship with PROM was explored as the mere definition of hernia usually reflect the does not patient's perception and complaint.

In this study, there was radiological evidence of PSH in 39.9% of patients while symptomatic and high-grade hernias were found in 34.4% and 17%, respectively. The incidence reported in this study is in concordance with previously published figures. Donahue *et al* reported an incidence of 48%

after 2 years of follow-up [3]. The authors attributed the increased detection rate to the use of the CT scan. In urologic literature, the incidence of PSH ranged from 7.7% to 48% depending on the method of diagnosis and the definition of the PSH [9,13,15,16]. Nevertheless, our figures should be interpreted cautiously as only patients attending during the pre-specified period were included and they had different follow-up periods.

It should be highlighted that most patients with radiological evidence of hernia were complaining regardless of the hernia grade. Therefore, this subset of patients should be critically evaluated and the impact on the quality of life should be extensively studied. In addition, we demonstrated a cumulative incidence that gradually steeps after approximately 10 years compared to the 3-year previously described time frame [17]. This difference might be because of the

Table 3.	Univariate analysis f	for factors predicting	radiologically-high-grade	parastomal hernia	after ileal	conduit urinary	diversion.
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Variable	Level	Low-grade (<i>n</i> = 287)	High-grade (<i>n</i> = 59)	<i>p</i> -Value
Gender	Male	228 (84.4)	42 (15.6)	
	Female	59 (77.6)	17 (22.4)	0.1
Chronic smokers	No	193 (86.2)	31 (13.8)	
	Yes	94 (77.0)	28 (23.0)	0.03
Obesity (BMI >30)	No	192 (81.4)	44 (18.6)	
,	Yes	95 (86.4)	15 (13.6)	0.2
Hypoalbuminemia	No	134 (87.0)	20 (13.0)	
	Yes	153 (79.7)	39 (20.3)	0.07
Coexisting hernia	No	276 (83.1)	56 (16.9)	
5	Yes	11 (78.6)	3 (21.4)	0.6
Previous hernia	No	257 (84.0)	49 (16.0)	
	Yes	30 (75.0)	10 (25.0)	0.1
Cell type	UC	193 (83.5)	38 (16.5)	
<i>,</i> ,	SCC	66 (83.5)	13 (16.5)	
	Adenocarcinoma	13 (76.5)	4 (23.5)	
	Others	15 (78.9)	4 (21.1)	0.8
pT stage	Organ confined	135 (81.3)	31 (18.7)	
1 3	Extra-vesical	139 (84.8)	25 (15.2)	0.4
pN stage	Negative	201 (79.1)	53 (20.9)	
1 5	Positive	71 (93.4)	5 (6.6)	0.004
Postoperative complications*	No	246 (82.3)	53 (17.7)	
	Yes	41 (87.2)	6 (12.8)	0.4
Wound dehiscence	No	256 (81.8)	57 (18.2)	
	Yes	31 (93.9)	2 (6.1)	0.1

Hernia grade is based on the European Hernia Society grading (EHS).

BMI: Body mass index; UC: Urothelial carcinoma; SCC: Squamous cell carcinoma.

Hypoalbuminemia: serum albumin < 3.5 g/dL.

*Postoperative complications were graded according to the modified Clavien system.

pT and pN stages were not available in 16 patients.

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Variable	Level	Asymptomatic ($n = 227$)	Symptomatic ($n = 119$)	<i>p</i> -Value
Gender	Male	181 (67.0)	89 (33.0)	
	Female	46 (60.5)	30 (39.5)	0.2
Chronic smokers	No	152 (67.9)	72 (32.1)	
	Yes	75 (61.5)	47 (38.5)	0.2
Obesity (BMI >30)	No	152 (64.4)	84 (35.6)	
	Yes	75 (68.2)	35 (31.8)	0.4
Hypoalbuminemia	No	115 (74.7)	39 (25.3)	
	Yes	112 (58.3)	80 (41.7)	0.001
Coexisting hernia	No	217 (65.4)	115 (34.6)	
-	Yes	10 (71.4)	4 (28.6)	0.6
Previous hernia	No	208 (68.0)	98 (32.0)	
	Yes	19 (47.5)	21 (52.5)	0.01
Cell type	UC	153 (66.2)	78 (33.8)	
	SCC	54 (68.4)	25 (31.6)	
	Adenocarcinoma	10 (58.8)	7 (41.2)	
	Others	10 (52.6)	9 (47.4)	0.5
pT stage	Organ confined	103 (62.0)	63 (38.0)	
	Extra-vesical	118 (72.0)	46 (28.0)	0.05
pN stage	Negative	164 (64.6)	90 (35.4)	
	Positive	52 (68.4)	24 (31.6)	0.5
Postoperative complications*	No	195 (65.2)	104 (34.8)	
	Yes	32 (68.1)	15 (31.9)	0.7
Wound dehiscence	No	203 (64.9)	110 (35.1)	
	Yes	24 (72.7)	9 (27.3)	0.4

BMI: Body mass index; UC: Urothelial carcinoma; SCC: Squamous cell carcinoma.

Hypoalbuminemia: serum albumin < 3.5 g/dL.

*Postoperative complications were graded according to the modified Clavien system.

pT and pN stages were not available in 16 patients..

nature of the longitudinal follow-up described by Hussein *et al* compared to the cross-sectional analysis in our study.

The main finding of this study was the significant association of hypoalbuminemia and the development of PSH. This was previously reported by Donahue et al. in a series of 433 patients [3]. Moreover, hypoalbuminemia was found to double the risk of incisional hernia in patients undergoing open bowel resection for inflammatory bowel disease [18]. Hypoalbuminemia is a potentially correctable factor and additionally, it is important in counseling the patient prior to surgery. Interestingly, we identified an organ-confined disease and negative lymph nodes as potential predictors of PSH formation. This might be attributed to the fact that patients with advanced disease were more likely to die earlier compared to those with organ-confined disease. The longevity of those patients puts them at increased risk of PSH development.

On analyzing the risk factors of developing symptomatic and high-grade hernias, previous surgery for hernia repair was a significant predictor. This was described by Liu and associates who found that patients with previous laparotomy were twice more likely to develop PSH on multivariate analysis [9]. It is recognized that previous laparotomies generally result in scarring and compromised blood supply to the anterior abdominal wall contributing to a weak musculature and increased liability for hernia development [19,20]. In addition, patients with a previous history for hernia were more susceptible to develop recurrent hernia possibly because of the generalized herniopathy related to a potential intrinsic defect of collagen [21].

A myriad of factors has been identified to contribute to the development of PSH even after robotic surgery. Among 383 patients who underwent robotic radical cystectomy, a cumulative incidence of 20% that became stationary after 3 years was reported. The authors identified longer operative time, larger fascial defect more than 3 cm, and lower postoperative renal function as independent predictors [17]. Other factors included female gender, severe obesity, chronic coughing, constipation, and radiation exposure [4,16]. On the other hand, in a retrospective review of approximately 1000 patients of radical cystectomy, PSH has not been associated with any of the preoperative parameters [22]. The discrepancy between the predictors of PSH among different series is reflected in our study in terms of inconsistent predictors when assessing dissimilar aspects of PSH. We believe that this observation requires a standardized method to identify consistent predictors among different studies.

Our study did not evaluate the surgical technique as a contributing factor to PSH as most of our procedures were done with a standard method. After performing the cruciate incision on the anterior rectus sheath, we split the rectus muscle to gain access to the peritoneal cavity. Then, the ileal conduit is fixed to both the anterior fascia and the posterior fascial and/or the peritoneum. Albeit anterior fascial fixation was believed to minimize PSH, Pisters and associates have found no difference between anterior fascial fixation and no fixation [5]. Furthermore, they found that patients with anterior fixation were twice as likely to develop PSH. The authors argued that the pattern of fascial fixation all around the IC apart from the medial aspect could have facilitated the development of medial hernia that expanded later. Furthermore, fascial tension required to place suture further weakened the fascia and facilitated PSH development.

Another crucial concern that is gaining attention is the role of the prophylactic mesh during radical cystectomy. Because of the higher incidence and increased morbidity of PSH repair, the prophylactic mesh has been proven safe and effective in randomized trials from the general surgery literature [4]. In an initial report by Donahue et al., the authors have fixed a prophylactic mesh at the time of IC in 40 female patients with body mass index more than 30. Despite having a short follow-up period, they did not report mesh-related complications and long-term results are awaited to establish

efficacy [4]. On the other hand, Tenzel et al. have used prophylactic mesh in a retro-rectus position in 18 patients who underwent robotic radical cystectomy [23]. The authors found neither PSH nor mesh-related complications at an average of 11-month follow-up. Recently, a randomized clinical trial has shown a hazard ratio of 0.4 (p = 0.02) for prophylactic mesh fixed at the time of radical cystectomy, and the authors have ascertained the beneficial effect of mesh fixation without increasing the risk of complications [24].

This study has several limitations that deserve mention. First, the potential of selection bias as many patients underwent IC at our institution has lost-to-follow-up or has been followed up in other hospitals. Nevertheless, we evaluated all of the attending patients without exclusion to minimize the selection bias. This is might also be attributed to the natural history after radical cystectomy especially when the average 5-year survival time is approximately 50% [25], and considering the relative aggressive pathology in patients with IC when compared to orthotopic bladder substitution. Another limitation was that validated questionnaires have not been used for evaluating the impact of PSH on patients' guality of life. Herein, we recommend developing and validating a questionnaire targeting those with PSH being significant morbidity after IC. Furthermore, the follow-up in this study was not longitudinal, so that the actual incidence of PSH could not be retrieved.

In conclusion, patient-reported symptoms are crucial to be evaluated as only a small proportion of patients with radiological evidence of PSH were asymptomatic. Preoperative hypoalbuminemia was the most significant factor contributing to the development and symptomatizing PSH. Previous hernia surgery further contributed to the patient complaint.

Disclosure statement

No potential conflict of interest was reported by the author(s).

ORCID

Ahmed M. Harraz b https://orcid.org/0000-0002-8902-517X Mohamed H. Zahran b https://orcid.org/0000-0002-2897-1023 Amr A. Elsawy b https://orcid.org/0000-0001-7077-8094 Mohamed A. Elbaset b http://orcid.org/0000-0001-5669-2999

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