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ORIGINAL ARTICLE

Trends in open abdomen management in Italy: a subgroup analysis from the IROA project

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Abstract

Use of open abdomen (OA) progressively acquired increasing importance with the diffusion of the damage control management of critical patients. The purpose of the present study is to identify the state of the art about the use of OA in Italy, focusing on techniques, critical issues and clinical outcomes. A prospective analysis of adult patients enrolled in the IROA, limited to the Italian participating centres was performed. 375 patients were enrolled. Mean age was 64 ± 16 years old, 56% of the patients were male, mean BMI was 26.9 ± 5.2. Main indications for using OA were secondary peritonitis (32.5%), post-operative peritonitis (22.9%) and trauma (11.7%). Main OA techniques used were commercial negative pressure wound therapy (49.6%) and Bogotà bag (27.7%). Definitive closure of the abdomen was reached in 82.4% of patients after 6 ± 7 days of OA. The primary fascia closure rate was 84.7%. Overall mortality was 29.1%. The complication rate was 50.8%, with an enteroatmospheric fistula incidence: 7.5%. A univariate analysis performed on complication type found the duration of OA treatment ($p = 0.024$) to be statistically significant. Univariate analysis on mortality risk identified as significant age, duration of OA (in days) and pancreatitis as indication; multivariate analysis confirmed age ($p < 0.001$) and pancreatitis ($p = 0.002$) as statistically significant. A large variety of behaviours towards the patient requiring OA exists. A strong acceptance of common, recognized and evidence-based guidelines is essential, to obtain more uniformity in patient management and coherence of collected data, thus leading to improvement in outcomes and reduction of costs.

Keywords Open abdomen · Management · Laparostomy · Complication · Mortality · Morbidity · Peritonitis · Pancreatitis · Trauma · Vascular emergency · Register · Fistula · IROA

Introduction

In recent years, the increasing attention on pathophysiological and clinical aspects of intra-abdominal hypertension (IAH) has led to major attention on use and regulation of open abdomen (OA). OA can be considered as a surgical strategy aimed to treat or prevent the physiological derange due to an increased abdominal pressure and the risk of consequent presentation of abdominal compartment syndrome (ACS). The use of OA progressively acquired more importance with the diffusion of the damage control management of critically injured or ill patients, through the use of damage control surgery (DCS) and damage control resuscitation (DCR) in presence of intra-abdominal severe bleeding, sepsis and/or risk factor for the development of ACS. Laparostomy, used primarily as treatment of ACS or secondarily as strategy of a DCS, brings all the challenges and the risks of a major procedure, because of its non-anatomical

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nature. Patients who undergoes OA management are at risk of developing severe complications, such as adhesion syndrome (frozen abdomen), enteric fistulas (especially entero-atmospheric fistulas—EAF), formation of abscesses and reduced rates of definitive fascial closure. Moreover, the persistence of a non-physiological status results in important loss of fluids and proteins, leading to the aggravation of catabolic physical response. Even considering the absence of definitive data regarding the time of re-operation, some studies [1–4] suggest an almost linear correlation between duration of OA and onset of complication; thus, focusing on early closure and use of strategies aimed to reduce the morbidity of OA is mandatory.

The purpose of the present study is to identify the state of the art about the use of OA in Italy, during the analysed period, focusing on techniques, critical issues and clinical outcomes.

Materials and methods

The present paper represents the Italian data derived from the IROA cohort study. IROA is a prospective observational international cohort study including patients with an OA treatment promoted by the World Society of Emergency Surgery (WSES) and the Pan-American Trauma Society (PTS). All the adult patients (more than 14 years old) treated with OA in Italy from September 2015 to August 2017 were included in the analysis. IROA data were recorded on a web platform (Clinical Registers®) through a dedicated web site: http://www.clinicalregisters.org. The study protocol was approved by the coordinating centre Ethical Committee (Papa Giovanni XXIII Hospital, Bergamo, Italy) and also registered to ClinicalTrials.gov (ClinicalTrials.gov Identifier: NCT02382770).

For each patient, we recorded demographical data, comorbidities, indication to the treatment, temporary abdominal closure technique (TACT) (in case of several techniques adopted, the most relevant was indicated, based on the duration), duration of the treatment, EAF formation, definitive closure and primary fascia closure rate, complications and mortality. Results were shown for all the patients and a subgroup analysis was performed for each indication.

Continuous variables were expressed as mean and standard deviation; categorical variables were expressed as proportion and percentage. Univariate analysis was performed with the Chi square test and the Mann–Whitney *U* test as appropriate; a multivariable logistic regression model was calculated with the variables associated with the outcome in the univariate analysis ($p < 0.05$). Results of the analysis were expressed as OR and 95% CI.

Results

From September 2015 to August 2017, 375 patients treated with OA in 13 different hospitals in Italy were collected. Tables 1 and 2 show the distribution of the patients among the participating centres.

Mean age was 64 ± 16 years old with 56% male and a mean BMI of 26.9 ± 5.2. The principal indication for OA was peritonitis (32.5%) followed by the post-operative peritonitis (22.9%) and trauma (11.7%). The preferred TACT was the commercial negative pressure wound therapy

Table 1 Description of the patients divided according to indications (general description and TACTs)

Indication	*n*	%	Age		Male gender		BMI		TACT											
									Bogotà bag		Skin closure		Wittmann patch		Barker vacuum pack		Commercial NPWT assisted		Commercial NPWT + dynamic tension	
			Mean	SD	*n*	%	Mean	SD	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Hemorrhage	34	9.1	68	14	22	64.7	25.30	3.18	12	35.3	2	5.9	1	2.9	3	8.8	16	47.1	0	0.0
Ischemia	30	8.0	72	8	17	56.7	26.65	7.28	10	33.3	1	3.3	0	0.0	2	6.7	16	53.3	1	3.3
Pancreatitis	23	6.1	62	14	13	56.5	29.48	5.60	9	39.1	1	4.3	0	0.0	2	8.7	10	43.5	1	4.3
Peritonitis	123	32.5	66	14	65	53.3	27.95	5.55	41	32.8	3	2.5	2	1.6	11	9.0	58	47.5	8	6.6
Post-op ACS	11	2.9	55	22	8	72.7	23.12	4.97	1	9.1	0	0.0	0	0.0	0	0.0	7	63.6	3	27.3
Post-op peritonitis	86	22.9	66	13	42	48.8	27.08	5.27	14	16.3	2	2.3	2	2.3	3	3.5	57	66.3	8	9.3
Trauma	44	11.7	48	21	34	77.3	25.42	3.12	11	25.0	17	38.6	0	0.0	2	4.5	11	25.0	3	6.8
Vascular emergencies	19	5.1	66	18	9	47.4	26.97	4.36	3	15.8	3	15.8	0	0.0	3	15.8	10	52.6	0	0.0
Other	5	1.3	63	6	2	40.0	23.38	4.47	3	60.0	0	0.0	0	0.0	0	0.0	1	20.0	1	20.0
Total	375	100.0	63.93	16.14	212	56.5	26.94	5.28	104	27.7	29	7.7	5	1.3	26	6.9	186	49.6	25	6.7

Table 2 Description of the patients divided according to indications (complications and mortality)

Indication	Death during "open"		Definitive closure		Fascia closure		Complications during "open"		Complications post-closure		Post-closure death		Overall mortality		EAF		Days of open abdomen		ICU length of stay		Ventilation days	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	Mean	SD	Mean	SD	Mean	SD
Hemorrhage	5	14.7	29	85.3	27	93.1	22	64.7	22	64.7	2	6.9	7	20.6	1	2.9	3	3	10	12	7	6
Ischemia	2	6.7	28	93.3	24	85.7	16	53.3	18	62.1	6	21.4	8	26.7	2	6.7	4	3	11	14	7	6
Pancreatitis	13	56.5	10	43.5	7	70.0	13	56.5	7	30.4	2	20.0	15	65.2	0	0.0	14	17	37	34	11	14
Peritonitis	16	13.1	107	86.9	93	86.8	70	56.6	58	47.5	20	18.9	36	29.5	8	6.6	5	4	10	11	7	7
Post-op ACS	4	36.4	7	63.6	4	50.0	8	72.7	5	45.5	0	0.0	4	36.4	0	0.0	7	7	18	20	10	11
Post-op peritonitis	12	14.0	74	86.0	56	77.8	49	57.0	52	60.5	7	9.5	19	22.1	12	14.0	8	8	13	14	8	7
Trauma	7	15.9	37	84.1	36	97.3	26	59.1	17	38.6	3	8.1	10	22.7	4	9.1	3	3	22	48	9	8
Vascular emergencies	7	36.8	12	63.2	10	83.3	14	73.7	9	47.4	3	25.0	10	52.6	0	0.0	5	6	12	15	9	7
Other	0	0.0	5	100.0	4	80.0	3	60.0	2	40.0	0	0.0	0	0.0	1	20.0	10	6	20	9	6	3
Total	66	17.6	309	82.4	261	84.7	221	58.9	190	50.8	43	13.9	109	29.1	28	7.5	6	7	13	22	8	7

(NPWT)-assisted technique (49.6%) followed by the Bogotà bag (27.7%). Overall mortality was 20.2% in Bogotà bag group and 33.9% in NPWT-assisted group. Mortality related to other techniques used is described in Table 3. Definitive closure of the abdomen was reached in 82.4% of the patients after a mean of 6 ± 7 days, with a primary fascia closure rate of 84.7%. A prosthesis was implanted in 46 (12.3%) of the patients, biological in the majority of the cases (67%).

Overall mortality was 29.1%, with 17.6% of the patients dying during the open phase and 13.9% of mortality following closure of the abdomen. Complications developed in 50.8% of the patients with 7.5% of EAF incidence.

A univariate analysis on complications identified the duration of OA treatment (4.19 ± 5.51 vs 6.19 ± 7.51, $p = 0.024$) as statistically significant.

A univariate analysis on mortality risk highlighted the statistical significance of three factors: age, days of OA and pancreatitis as indication; the multivariate analysis confirmed age ($p < 0.001$) and pancreatitis (0.002) as statistically significant.

Tables 1 and 2 show the results in detail with the subgroup analysis per indication and Table 3 shows results in detail per indication and TACT adopted. Results of univariate and multivariate analysis are shown in Table 4.

Discussion

Used as a bridge strategy between two sequential procedures or as a primary measure to treat ACS, OA can be considered at present a well-known and practiced method with several indications. This leads to a variety of different situations where the OA becomes part of the therapeutic strategy. In the study, we can observe that the majority of cases are represented by peritonitis (primary or post-operative) with 209 cases out of 375 (55.7%). The use of OA in abdominal sepsis or severe contamination, even if considered as an option and not as an absolute indication [5–9], seems to be part of the common practice. Patients with peritonitis are often clinically complex, with compromised physiological status. Thus, the need to shorten the time of surgery brings about the necessity of a damage control strategy, with the possibility of undertaking more accurate and refined proceedings after appropriate resuscitation. In these cases, OA is the choice to gain the needed time and reduce the risk of ACS. Life-threatening conditions and elevated risk of developing ACS, such as in severe trauma, pancreatitis and catastrophic vascular emergencies, are often indications to a DCS, with OA as a consequence.

In the present study, several TACTs have been used by the participants. They can be divided into two major groups: passive systems (Bogota bag, skin closure, Wittmann patch) and active systems (Barker vacuum pack and commercial

Table 3 Indications and results divided according to TACT used

Indication	*n*	%	Days of open abdomen		Mortality		EAF	
			Mean	SD	*n*	%	*n*	%
Hemorrage								
TACT								
Bogotà bag	12	35.29	2	1	4	33.3	0	
Skin closure	2	5.88	2	0	0		0	
Wittmann patch	1	2.94	14		1	100.0	0	
Barker vacuum pack	3	8.82	4	1	0		0	
Commercial NPWT assisted	16	47.06	4	2	2	12.5	1	6.3
Commercial NPWT + dynamic tension	0				0		0	
Total	34	100	3	3	7	20.6	1	2.9
Ischemia								
TACT								
Bogotà bag	10	33.33	3	2	1	10.0	0	
Skin closure	1	3.33	1		1	100.0	0	
Wittmann patch	0				0		0	
Barker vacuum pack	2	6.67	7	6	0		0	
Commercial NPWT assisted	16	53.33	4	3	6	37.5	2	12.5
Commercial NPWT + dynamic tension	1	3.33	7		0		0	
Total	30	100	4	3	8	26.7	2	6.7
Other								
TACT								
Bogotà bag	3	60.00	6	2	0		0	
Skin closure	0				0		0	
Wittmann patch	0				0		0	
Barker vacuum pack	0				0		0	
Commercial NPWT assisted	1	20.00	17		0		0	
Commercial NPWT + dynamic tension	1	20.00	15		0		1	100.0
Total	5	100	10	6	0		1	20.0
Pancreatitis								
TACT								
Bogotà bag	9	39.13	10	7	6	66.7	0	
Skin closure	1	4.35	80		0		0	
Wittmann patch	0				0		0	
Barker vacuum pack	2	8.70	25	0	2	100.0	0	
Commercial NPWT assisted	10	43.48	6	6	7	70.0	0	
Commercial NPWT + dynamic tension	1	4.35	15		0		0	
Total	23	100	14	17	15	65.2	0	
Peritonitis								
TACT								
Bogotà bag	40	32.79	4	3	8	20.0	0	
Skin closure	3	2.46	7	5	0		0	
Wittmann patch	2	1.64	5	4	1	50.0	0	
Barker vacuum pack	11	9.02	4	3	4	36.4	1	9.1
Commercial NPWT assisted	58	47.54	5	5	20	34.5	7	12.1
Commercial NPWT + dynamic tension	8	6.56	5	5	3	37.5	0	
Total	122	100	5	4	36	29.5	8	6.6
Post-op ACS								
TACT								
Bogotà bag	1	9.09	1		0		0	
Skin closure	0				0		0	

Table 3 (continued)

Indication	*n*	%	Days of open abdomen		Mortality		EAF	
			Mean	SD	*n*	%	*n*	%
Wittmann patch	0				0		0	
Barker vacuum pack	0				0		0	
Commercial NPWT assisted	7	63.64	9	8	3	42.9	0	
Commercial NPWT + dynamic tension	3	27.27	4	0	1	33.3	0	
Total	11	100	7	7	4	36.4	0	
Post-op peritonitis								
TACT								
Bogotà bag	14	16.28	3	1		0	2	14.3
Skin closure	2	2.33	3	1	0		0	
Wittmann patch	2	2.33	6	0	0		0	
Barker vacuum pack	3	3.49	6	4	1	33.3	0	
Commercial NPWT assisted	57	66.28	10	10	16	28.1	9	15.8
Commercial NPWT + dynamic tension	8	9.30	7	4	2	25.0	1	12.5
Total	86	100	8	8	19	22.1	12	14.0
Trauma								
TACT								
Bogotà bag	11	25.00	4	3	1	9.1	3	27.3
Skin closure	17	38.64	3	2	5	29.4	1	5.9
Wittmann patch	0				0		0	
Barker vacuum pack	2	4.55	3	1	1	50.0	0	
Commercial NPWT assisted	11	25.00	4	5	3	27.3	0	
Commercial NPWT + dynamic tension	3	6.82	2	1	0		0	
Total	44	100	3	3	10	22.7	4	9.1
Vascular emergencies								
TACT								
Bogotà bag	3	15.79	5	6	1	33.3	0	
Skin closure	3	15.79	9	10	1	33.3	0	
Wittmann patch	0				0		0	
Barker vacuum pack	3	15.79	2	1	2	66.7	0	
Commercial NPWT assisted	10	52.63	5	6	6	60.0	0	
Commercial NPWT + dynamic tension	0	0.00			0		0	
Total	19	100	5	6	10	52.6	0	
Total								
TACT								
Bogotà bag	104	27.73	4	4	21	20.2	5	4.8
Skin closure	29	7.73	6	15	7	24.1	1	3.4
Wittmann patch	5	1.33	7	4	2	40.0	0	
Barker vacuum pack	26	6.93	6	6	10	38.5	1	3.8
Commercial NPWT assisted	186	49.60	6	7	63	33.9	19	10.2
Commercial NPWT + dynamic tension	25	6.67	6	5	6	24.0	2	8.0
Total	375	100	6	7	109	29.1	28	7.5

Table 4 Results of univariate and multivariate analysis

	Univariate analysis		Multivariate analysis	
	OR	*p*	OR	*p*
Age	1.031 (1.015–1.04)	< 0.001	10.3 (1.01–1.05)	< 0.001
Days of open abdomen	1.03 (1.01–1.05)	0.049	1.036 (0.98–1.05)	0.3
Pancreatitis	5.14 (2.11–12.05)	< 0.001	4.81 (1.82–12.73)	0.002

negative pressure wound therapy—NPWT—with or without dynamic tension). Passive systems represent 36.8% of the total (138 of 375); some authors [5, 6] suggest that the use of passive systems (Bogota bag in Primis) should be limited to low resource settings, accepting a lower rate of delayed fascial closure and a major risk of EAF. While in peritonitis and post-operatory peritonitis, the active systems represent the majority, in trauma we can notice that most patients are treated with Bogota bag (25%) and skin closure (38.6%); DCS, especially in case of hemodynamically unstable traumatized patients, can require rapid, functional measures and simple passive systems (as skin closure) can give the surgeon the sensation to be more "time-effective".

The incidence of EAF is similar to the one described in literature [8, 10, 11]: in fact, the overall incidence is 7.5%. The incidence of EAF with passive systems seems to be lower than the one obtained using active systems (9.3% vs 4.3%), but this could be explained in several ways: preference for NPWT in severe cases and contaminated surgical fields, preference for passive systems when a shorter time of OA is already planned since the first intervention. Preliminary results of the IROA, focused on EAF, showed that formation of EAF is not connected with the presence of active suction, but with duration of the treatment, state of nutrition and presence of cancer [12, 13].

Half of the patients had complications in the post-closure period. More than half of them started having complications during the open period (58.9%). The univariate analysis corroborates the data: there is significative correlation between duration of OA and onset of complications ($p = 0.024$), as known from previous studies [1–4, 8, 13].

The ICU length of stay is influenced by the severity of the condition and so is the mean time of mechanical ventilation: trauma and pancreatitis are the pathologies with the longest average period in ICU.

Overall mortality in the examined group is 29.1% (109 of 375). Furthermore, as described in the results, it seems that the most used passive system is burdened by the lowest mortality than the most used active system (Bogotà bag 20% vs commercial NPWT 33%). Raw data need to be analysed: as already shown for ICU length of stay, we must consider different outcomes of different pathologies. Patients with severe pancreatitis or vascular emergency who underwent OA in this study had, respectively, 65.2% and 52.6% mortality. If we consider standard mortality of these two clinical entities (especially associated with ACS), we reach similar percentages [14] without the use of OA. This is strengthened by the statistical analysis: univariate analysis shows as significant factors related to mortality: age, duration of treatment and pancreatitis (Table 4); multivariate analysis confirmed age and pancreatitis as statistically significant. Considering the choice of the TACT, we must consider the presence of different attitudes towards the need of undergoing an OA procedure: the surgeon is for sure influenced by her/his experience, by intraoperative assessment of severity of pathology and by availability of resources. Different rates of mortality and complications according to different TACTs used could be influenced by gravity of condition, reserving more expensive and complex systems (such as NPWT) for more compromised or at-risk patients. Further studies are needed to precisely evaluate in which way OA directly influences the pathology-related mortality of the patient and which factors should affect the TACT choice during procedures.

Post-operative ACS is a different pathological entity that can be considered as self-standing indication for OA after the failure of medical step-up approach. In present cohort, one-third of patients died because of this condition occurred after OA treatment and all these patients died during the open phase. This can be explained considering the very same indication to OA in post-operative ACS: while a period in OA after DCS is not assurance of solving the underlying condition, in case of ACS the necessity of OA stands as long as we cannot close the fascia without giving again rise to ACS. In other words, the definitive closure is possible only when the condition that gave indication to OA is solved. The high mortality and morbidity of the condition are, of course, a strong indication to consider the measurement of IAP part of the common practice in ICU, especially in patients at risk of developing ACS.

Conclusions

A large variety of attitudes and behaviours towards the patient with conditions requiring OA exists. A strong acceptance of common, recognized and evidence-based guidelines is required to obtain more uniformity in patient management and a focused coherence of data, thus leading to improvement in outcomes and reduction of costs.

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Compliance with ethical standards

Conflict of interest All authors declare that they have no conflict of interest.

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Research involving human participants and/or ani No animal and/or humans have been involved in the reserach.

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