The International Register of Open Abdomen (IROA): An occasion to better understand the pediatric open abdomen - Preliminary results and call for pediatric intensive care participants

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Abstract

In pediatric patients open abdomen (OA) is applied with many and not standardized indications. Several studies have been published regarding the OA management in adults and fewer in pediatrics. Several issues are still unclear and need more high quality data. The World Society of Emergency Surgery (WSES) promoted the International Register of Open Abdomen (IROA) dedicated to adults and pediatric patients. The register is held on a web platform (Clinical Registers®) through a dedicated web site: www.clinicalregisters.org. (ClinicalTrials.gov Identifier: NCT02382770).

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Therapeutical note

In pediatric patients open abdomen (OA) is applied with many and not standardized indications. The OA management is complex and challenging requiring a multidisciplinary approach.[1,2] Up to the OA introduction surgeons have been tried to *close at any cost* the abdomen; actually a combination of medical and surgical therapies have been introduced as negative pressure wound therapy and dynamic closures leading to a great improvement in outcomes (*i.e.*, morbidity, mortality, incisional hernia rate). Several studies have been published regarding the OA management in adults. The Abdominal Compartment Society (WSACS) proposed specific definition for pediatric intra-abdominal hypertension (IAH) and abdominal compartment syndrome (ACS),[3] but several issues about ACS management and treatment are still unclear in pediatric population.[4] Contrasting data about the limits of indications, applications and methods to close the OA are still matter of debate. The differences between the different techniques to maintain the OA in terms of morbidity and mortality have still to be investigated. Large cohorts of homogeneous patients are lacking. Moreover no definitive data exist about nutrition strategies. Lastly not enough data regarding the closure and follow-up exist.

To overcome this lack of high level of evidence data the World Society of Emergency Surgery (WSES) promoted the International Register of Open Abdomen (IROA) dedicated to adults and pediatric patients.[4] This prospective observational trial aims to enroll patients undergone to OA procedure and prospectively investigate morbidity and mortality up to 1-year follow-up, with more than 100 clinical variables divided into pre-, intra- and post-operative, dressing, nutritional and f-up data. The register is held on a web platform (Clinical Registers®) through a dedicated web site: www.clinicalregisters.org to allow to surgeons and physicians members of Intensive Care Unit (ICU) teams treating with OA patients to participate from the whole world. The only necessity is a computer and a web connection. The data insertion will be possible after the registration to the web platform. Each researcher will get personal credentials that will allow him/her to register patients. Data will be kept protected by a certified system of data encryption.

Table 1. General characteristics of the paediatric patients enrolled in IROA (data are shown as percentages and mean standard deviation).

Age classes (years)	0-1	2-5	6-10	11-17	Total
N	30	9	6	12	57
Age	0.64±0.34	2.97±0.53	7.89±0.75	14.89±1.74	4,79±5,79
Indication					
Peritonitis	5/30	1/9	1/6	0/12	6/57
Liver trasplant	17/30	3/9	3/6	6/12	29/57
Trauma	0/30	0/9	1/6	0/12	1/57
Vascular emergencies and hemorrage	1/30	1/9	1/6	2/12	4/57
Post-operative ACS	3/30	3/9	0/6	1/12	8/57
Other	4/30	1/9	1/6	3/12	9/57
Days of open abdomen	5,17±6,86	3.42±3.82	27.16±41.66	4.44±3.39	7.44±16.16
EAF		0/30	0/9	0/6	1/12 2/57
Mortality	3/30	1/9	1/6	3/12	8/57
ICU days	36,29±35,18	8.33±4.84	38±59.56	26.33±36.01	31.14±37.11
Ventilation days	26,88±30,56	7.57±6.55	15.66±16.39	8.44±7.28	19.36±24.99
TACT					
Bogotà Bag	7/30	3/9	1/6	2/12	13/57
Skin Closure	0/30	0/9	1/6	0/12	1/57
Barker	8/30	3/9	1/6	2/12	15/57
Commercial NPWT	15/30	3/9	3/6	8/12	28/57
Definitive closure	29/30	8/9	6/6	9/9	52/57
Primary fascial closure	28/29	8/8	6/6	9/9	51/52

ACS, abdominal compartment syndrome; EAF, entero-atmospheric fistula; ICU, Intensive Care Unit; TACT, temporary abdominal closure technique; NPWT, negative pressure wound closure.

The IROA protocol has been approved by the coordinating center Ethical Committee (Papa Giovanni XXIII Hospital, Bergamo, Italy) and from Hannover Medical School one. IROA has a ClinicalTrials.gov Identifier: NCT02382770. All documents can be downloaded from www.clinicalregisters.org.

At present, during its first 24 months IROA enrolled 740 patients; 55 centers from 4 continents are participating. The 57 pediatric patients from 4 Pediatric-ICU are summarized in Table 1. The OA in pediatrics is less frequent than in adults but existing data suggest the necessity to increase our knowledge either in children. IROA could potentially represent the way to improve our understanding in pediatrics and to potentially increase our therapeutic tools and intensive care management.

Present letter aims to present the preliminary encouraging results and to warmly invite all surgeons and intensivists who perform and manage with OA procedures in pediatrics to participate to IROA that represents at the moment the first pediatric non-profit international effort.

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