Clinical strategies for the management of intestinal obstruction and pseudo-obstruction: a Delphi consensus study from the Società Italiana di Chirurgia d’Urgenza e del Trauma (SICUT)

Gianluca Costa MD PhD, Paolo Ruscelli MD, Genoveffa Balducci MD, Francesco Buccoliero MD, Laura Lorenzon MD PhD, Barbara Frezza MD, Piero Chirletti MD, Stefano Miniello MD, Francesco Stella MD, Franco Stagnitti MD, and the OBOW - SICUT Collaborative Study Group

1 Emergency Surgery Unit, Surgical and Medical Department of Translational Medicine, Sant’Andrea Hospital, Faculty of Medicine and Psychology, University of Rome “La Sapienza”
2 Emergency Surgery Unit, Torrette Hospital, Faculty of Medicine and Surgery, Polytechnic University of Marche, Ancona
3 Emergency Surgery Unit, M. Bufalini Hospital, AUSL Cesena
4 Department of Surgical Sciences, Umberto I Hospital, Faculty of Medicine and Odontology, University of Rome “La Sapienza”
5 Department of Sciences and Medical - Surgical Biotecnology, Polo Pontino Terracina, Faculty of Pharmacy and Medicine, University of Rome “La Sapienza”
6 Emergency and Trauma Surgery Section, Department of Applications and Innovative Technologies for Surgery, Faculty of Medicine and Surgery, University of Bari
7 Hospital General Direction, Epidemiologist, Director of Hospital Medical Data Archiving System, Sant’Andrea Hospital, Faculty of Medicine and Psychology, University of Rome “La Sapienza”
8 OBOW-SICUT Collaborative Study Group, see Appendix 1

Corresponding author.

Running title. Delphi technique and intestinal obstruction

Competing interests. None of the authors has any potential financial conflict of interest related to this manuscript.

Word Count. Abstract: 266 words; Main document: 3546 words.
Abstract

**Background.** Intestinal obstructions/pseudo-obstruction of the small/large bowel are frequent conditions but their management could be challenging. Moreover, a general agreement in this field is currently lacking, thus SICUT society designed a consensus study aimed to define their optimal workout.

**Methods.** The Delphi methodology was used to reach consensus among 47 Italian surgical experts in two study rounds. Consensus was defined as an agreement of 75.0% or greater. Four main topic areas included nosology, diagnosis, management and treatment.

**Results.** A bowel obstruction was defined as an obstacle to the progression of intestinal contents and fluids generally beginning with a sudden onset. The panel identified four major criteria of diagnosis including absence of flatus, presence of >3.5 cm ileal levels or >6 cm colon dilatation and abdominal distension. Panel also recommended a surgical admission, a multidisciplinary approach and a gastrografin swallow for patients presenting occlusions. Criteria for immediate surgery included: presence of strangulated hernia, a >10 cm cecal dilatation, signs of vascular pedicles obstructions and persistence of metabolic acidosis. Also, rules for non-operative management (to be conducted for maximum 72 hours) included a naso-gastric drainage placement and clinical and laboratory controls each 12 hours. Non-operative treatment should be suspended if any suspects of intra-abdominal complications, high level of lactates, leukocytosis (>18.000/mm$^3$ or Neutrophils >85%) or a doubling of creatinine level comparing admission. Conversely, consensus was not reached regarding the exact timing of CT scan and the appropriateness of colonic stenting.

**Conclusions.** This consensus is in line with current international strategies and guidelines, and it could be a useful tool in the management of these common and peculiar diseases.

**Keywords.** Intestinal obstruction; pseudo-obstruction; small bowel obstruction; large bowel obstruction; Delphi study.

Riassunto
Premessa. Le ostruzioni e pseudo-ostruzioni del piccolo/grande intestino sono condizioni frequenti, ma la loro gestione risulta spesso difficile. Inoltre, in questo campo manca un consenso gestionale, pertanto la Società Italiana di Chirurgia d’Urgenza e del Trauma (SICUT) ha disegnato uno studio volto a definire il loro management ottimale.

Metodi. Lo studio è stato condotto utilizzando la metodologia Delphi coinvolgendo un panel di 47 chirurghi italiani con maturata esperienza clinica. Il consenso è stato definito come un accordo uguale o superiore al 75.0%. Lo studio si è focalizzato su quattro aree tematiche comprendenti la nosologia, la diagnosi, la gestione e il trattamento delle ostruzioni e delle pseudo-ostruzioni intestinali.

Risultati. Un occlusione intestinale è stata definita come un ostacolo alla progressione del contenuto intestinale in genere ad esordio improvviso. Il panel ha identificato quattro principali criteri di diagnosi, tra i quali l’assenza di canalizzazione ai gas, la presenza di livelli ileali > 3.5 cm o di una dilatazione del colon > 6 cm nonché di una distensione addominale. Viene inoltre consigliato il ricovero in chirurgia, un approccio multidisciplinare e un transito con Gastrographin per tutti i pazienti che presentano un’occlusione. Tra i criteri per un intervento chirurgico immediato sono inclusi: la presenza di un’ernia strozzata, una dilatazione del cieco > 10 cm, segni di ostruzione del peduncolo vascolare e la persistenza di acidosi metabolica. La gestione non operatoria dei pazienti (la cui durata massima dovrebbe essere di 72 ore) include il posizionamento di un sondino naso-gastrico e la necessità di effettuare controlli clinici e laboratoristici ogni 12 ore. Il trattamento non operatorio deve essere sospeso in caso insorga il sospetto di complicanze intra-addominali, compaia un alto livello di lattati, una leucocitosi (> 18.000 / mm3 o neutrofili> 85%) o un raddoppiamento del livello di creatinina rispetto ai valori basali al ricovero. Al contrario il panel non ha raggiunto alcun consenso riguardo l’esatta tempistica della TAC e l’opportunità di stenting del colon come intervento palliativo in attesa di chirurgia definitiva.

Conclusioni. Le raccomandazioni stabilite sono in linea con le strategie e le linee guida internazionali, e potrebbero essere uno strumento utile per la gestione del paziente affetto da occlusione intestinale.

Parole chiave. Occlusione intestinale; pseudo-occlusione intestinale; consenso secondo Delphi.
Intestinal obstructions of the small/large bowel are very common diseases, accounting around the 15% of all emergency visits for acute abdominal pain and causing approximately 300,000 hospital admissions each year in North America.

Although common, an intestinal obstruction could be a severe condition, since its complications may include life-threatening diseases such as bowel ischemia or intestinal perforation.

Intestinal obstructions are usually classified on the basis of the bowel occlusion location, thus they could be differentiated into small bowel obstructions (SBO) or large bowel obstructions (LBO).

About 75% of the SBO are caused by peritoneal adhesions which could be formed following a laparotomy. Indeed, even though any surgical procedure may predispose to the formation of adhesions, interventions at the lower abdomen or at the pelvis sites are those more frequently complicated by the development of adhesive bands, especially if the peritoneal cavity has been contaminated with the enteric fluids or purulent collections.

Typical presentation of patients with SBO include abdominal distention, vomiting and crampy abdominal pain.

Opposite, patients with large bowel obstructions (LBO) usually present with abdominal pain, distention and constipation, while vomit is less common and usually presents lately.

Of note, the severity of presentation and vomit characteristics of both SBO and LBO may vary according with the site and the degree of obstruction.

LBO usually affect the elderly and more than 50% of the cases are due to colorectal cancers. Volvulus accounts for another 10–17% of LBO, occurring more frequently in the sigmoid colon or in the cecum. Diverticular strictures or complications of acute diverticulitis, such as abscess, are the cause of about 10 % of LBO.

Other less frequent causes of SBO and LBO include radiation therapy, Crohn’s disease, intussusceptions, ischemia, gallstone and bezoars.

Symptoms of SBO and LBO can simulate a peculiar disease called intestinal “pseudo-obstruction”. This term was first introduced more than 60 years ago by Dudley and associates who investigated a small case-series of patients with an obstruction unexplained by any mechanical cause, thus the diseases was referred as spastic ileus. Currently, a “pseudo-obstruction” is defined as a disease characterized by clinical and radiological symptoms and signs of an intestinal obstruction, without evidence of any lesions occluding the gut lumen.

Acute colonic pseudo-obstruction (ACPO), also called acute colonic ileus or Ogilvie’s syndrome, was first described in 1948 by Sir Heneage Ogilvie. Although the exact etiology is still unclear, it has been hypothesized that an excessive sympathetic stimulation, combined with suppressed parasympathetic activity, leads to a
state of adynamic ileus. ACPO is most frequent in males and patients are mostly elder and hospitalized. Symptoms usually develop over a few days and are similar to those of a true obstruction, including abdominal distention, pain, nausea, and vomiting, even though the alvus may range from obstipation to paradoxical diarrhea \(^3\):\(^{16-19}\).

Even if the morbidity and mortality due to intestinal obstructions declined since the introduction of more sophisticated diagnostic tests and imaging work-out, these conditions remain a challenge for those clinicians who have to assess a proper diagnosis \(^7\). Furthermore, it is important to highlight that a consensus agreement related to the clinical approach to patients presenting with a suspected bowel obstruction is currently lacking \(^20\) and powered randomized controlled trials are presently scant.

On the basis of this background, this study was designed aiming to reach a consensus strategy among a group of Italian national experts, regarding the optimal clinical management of patients presenting with intestinal obstruction or pseudo-obstruction.

For the purpose of the study, the Italian Society of Emergency and Trauma Surgery (SICUT) nominated a panel of experts who were consulted using the Delphi methodology. This approach, named after the Oracle at Delphi, is an internationally validated group facilitation technique that searches for a consensus through a series of interview rounds, and allows the collection of experts’ opinions without the need to bring people physically together; moreover, following each round, each participant is able to reconsider his/her answers in the light of the views expressed by others \(^21\)-\(^25\).

**Materials and Methods**
Study Design. Study began on March 2015 when the SICUT board society members identified two study coordinators (GC and PR) who selected the topics for the Delphi study through a bibliographic search. Indeed, for the purpose of the choice of methodology, the topics selection, and for the results publication, a computer search of the National Library of Medicine MEDLINE database (PubMed) was performed in March 2015 and extended to January 2016 using the following search strings:


Search strategy for #Meth provided 98 items. Search strategy for search #1 provided 177 papers, otherwise search #2 and search #3 provided 139 and 100 manuscripts respectively.

Analogous searches covered the Cochrane Collaboration and the Google Scholar databases in order to gather all the remaining evidence, synopses and guidelines on the topic.

One author (LL) collected literature data while the two authors coordinators (GC and PR) evaluated papers independently. Significant references from the retrieved publications were also included. The study coordinators were blinded to authors’ and journals’ names while reviewing the series, and did not have any direct contact with the authors of the included papers. Coordinators did not consider any journal’s scores (e.g., journal’s Impact Factors) of published articles as exclusion criteria. Each paper retrieved was assessed for possible inclusion or exclusion in our study, primarily by revision of titles and/or abstracts and finally after reading the article; furthermore, duplicate references were removed by manual search. Publications with English language abstract not available and/or of low interest in the specific topics and key questions were not took into consideration. Whenever possible, the papers were classified for evidence strength following the Oxford CEBM 2011 scheme.
This methodology provided the selection of a total of XX (Appendix 2) manuscripts focused on methodology and on 4 main topic areas to structure the questionnaires (nosology, diagnosis, management, treatment), regarding: SBO caused by adhesions or other conditions, LBO due to cancer or other causes and pseudo-obstructions by adynamic ileus or Ogilvie’s syndrome.

Panel of experts. On April 2015 the SICUT society board members approved the panel selected by the two coordinators. The panel included the members of the SICUT board, those Italian emergency surgeons with at least 5 years of personal experience and with outstanding research qualities retrieved from the literature search and qualified members of surgical Italian Departments with clinical-scientific background in this field supported by the others selected members (the so called snowball referral). Of note, there are no clear guidelines regarding the number of experts to be included, but, for the purpose of this study, a panel size of at least 30 experts was considered appropriate. Invitations were then mailed to 40 surgical centres (3 declined). Accordingly, a collaboration group of experts willing to participate, was constituted and named “OBOW (Obstructive-Bowel) SICUT Collaborative Study Group” (see Appendix 1).

Questionnaires and Rounds. According to the Delphi methodology an un-defined number of rounds can be performed until a consensus has been reached among the experts, but as outlined in Figure 1, the present study consisted of two rounds.

Before the first round launch, an external colleague (FS) not experienced in Delphi methodology, was asked to test the feasibility and the comprehension of the methodology and questionnaires. Questionnaires were e-mailed to all participants in both rounds. Reminders were sent to non-responders on a regular basis, with a maximum of three reminders per person.

Questionnaires of both rounds consisted of three parts: nosology, diagnosis and treatment strategies. The participants were asked to answer assuming that all required facilities and an adequate clinical setting were at one’s disposal (i.e. 24/7h availability of CT scan, interventional radiologists, operation theaters and emergency surgeons). Questionnaires were designed with different type of answers such as yes or no, check-off or open and Likert scale. The latter ranged from 1: complete disagreement to 7: complete agreement.

The first round consisted of 23 items (including 98 variables) and the second round consisted of 12 items (including 47 variables). The first round questionnaire ended on May 2015; following, results were analyzed and a second questionnaire was developed on August 2015. Second round ended on October 2015. Of note, during the second round, remarks and suggestions of the first round were also incorporated, but questions where consensus was reached in the first round were omitted. During SICUT national congress held
in Milan on October 2015, the final results were presented, discussed and approved by the panel of experts. Accordingly, the following features of a consensus method were further applied: anonymity, iteration, controlled feedback, and statistical group response.

Statistical Analysis and Reporting of Questions. For the purpose of data collection and analysis a SPSS Database was constituted by one author (BF) using the 17.0 version of the PASW Statistics Program (SPSS Italy, Bologna) for MacOSX. Data from the two rounds of questions were reported and analyzed separately. Consensus was defined as an agreement equal or greater than 75% between respondents (number of identical answers divided by the number of respondents) or a mean value of 5.26 of the Likert scale, thus corresponding to a value >75% out of 7.

Results
Participants. During a 6-month period, 33 out of 37 centres invited (89.1%), including 47 surgeons with clinical and scientific expertise in emergency abdominal surgery, filled out the first round questionnaire. Following 25 out of 33 centres participants (75.7%) completed the second round.

Consensus agreement. Figure 2 reports different types of agreement that were obtained through the survey, whereas Table 1 reports only results of where strong consensus was reached. The first round provided some items of uncertain consensus regarding the timing of CT abdominal imaging in SBO along with the use of contrast medium both oral and/or e.v, thus these items were not included in this report. Table 1 summarizes results of the Delphi study: accordingly, a bowel obstruction was defined as an obstacle to the progression of intestinal contents and fluids generally beginning with a sudden onset with a consensus of 80.4%. Consensus was reached also regarding type of diagnosis, both clinical and radiological. Accordingly, the panel identified four major criteria (absence of flatus, presence of >3.5 cm ileal levels, a colon dilatation >6 cm, and the presence of an abdominal distension) and one minor criteria (absence of stool passage), whereas a presentation with “abdominal pain” reached exclusively a moderate agreement (73.4%) as minor criteria. Clinical rules for diagnosis should include at least one major criteria, however the work-out should include also a radiological evaluation, performed with X-Rays (first choice modality) and CT scan for patients presenting with LBO and pseudo-obstruction, otherwise upon clinical judgement in case of SBO. The vast majority of the items focused on the clinical management were considered unanimously, as the need of a surgical department admission, a multidisciplinary evaluation approach and the recommendation for a gastrografin swallow. Conversely, even if clinical scores (e.g. APACHE-II and P-POSSUM) were overall considered useful in risk assessment, the value of the ASA score reached just a mild agreement (74.1%). On the same extent, the consensus was only moderate with respect of the endoscopic decompression and the prostigmin treatment for patients presenting intestinal pseudo-obstructions (respectively 74.4% and 72.4%). Furthermore, criteria for immediate surgery were quite mandatory for all surgeon interviewed with respect of hernia strangulation, a cecal dilatation >10 cm, signs of mesenteric pedicle vascular obstructions and the persistence of a metabolic acidosis. However, the panel showed minor agreement regarding a localized Blumberg sign (66.7%), the presence of a continuous and spontaneous pain (66.7%) and CT signs of modified bowel enhancement (66.7%) or caliber modifications (69.7%). Of note, rules for non-operative management (NOM - to be performed for a maximum of 72 hrs) included a naso-gastric drainage placement and clinical and laboratory controls each 12 hrs, but the use of antibiotics was not considered a standard (agreement 55.5%).
Nevertheless, the panel agreed in suspending the NOM if any suspects of intra-abdominal complications, in case of high level of lactates, WBC, creatinine of fever, Table 1.

**SBO and LBO clinical management.** On the basis of the agreement reached within the present study, the OBOW Consensus Study group developed two clinical management flow-charts for those patients admitted to a surgical ward with a diagnosis of SBO (Figure 3) and LBO (Figure 4). For the latter category, it is important to highlight that it was not reached a general agreement among surgeons, regarding the utility of the colonic stent as a bridge to surgery. Indeed the panel felt necessary the evaluation and referral for its appropriateness to a specialized GI endoscopist who will perform the procedure in relation to the location of the obstruction and patient’s performance *status*. Accordingly, this option has been taken into account in the flow-chart but not included in the consensus agreement.
This study reports a consensus agreement regarding the clinical management of SBO, LBO and intestinal pseudo-obstruction that has been developed using the Delphi methods among a panel of Italian experts. The research has been conducted strictly adhering to the methodology recommendations stated by Hasson and co-authors and including: a clear explanation of the clinical problem and rationale and of the literature review, detailed report of the methods (experts selection process, number of rounds performed, statistical analysis) and results (response rate for each round, consensus and issues regarding dis-agreement) 28. The main advantage of the Delphi method is the achievement of consensus in a given field when there is a lack of empirical evidence. The Delphi has been described as a quick, inexpensive and efficient way to combine the knowledge and abilities of a group of experts, although others argued that extensive time commitment is needed. A key issue of this approach is the panel selection: indeed, the Delphi method does not call for an expert panel to be a representative sample for statistical purposes, but qualities of the experts selected seem to be more important rather than its number 29. Sackman also stressed that one of the key principles of the Delphi, the anonymity, may also encourage hasty decisions 30. The Delphi approach is particularly attractive for the task of achieving consensus, especially among health care professionals, however, the determination that a consensus has been finally achieved requires also an operational definition. Although this notion of consensus is fundamental to all the Delphi studies, the definition of what constitutes consensus is nevertheless less clear. According to a recent systematic review conducted by Diamond and associates, the most common definition for consensus among studies using the Delphi method, was a percent agreement, with 75% being the median threshold, thus consistent with our approach 31. The present manuscript focused in particularly on intestinal obstruction. An acute gastrointestinal obstruction occurs when the normal course of intestinal contents is interrupted. The obstacle can occur at any level throughout the gastrointestinal tract, thus signs and symptoms may change accordingly. An early recognition of the condition and the establishment of an appropriate treatment are consequently mandatory. Usually, the diagnostic process involves imaging including X-Rays, ultrasonography and CT scans 32. The OBOW (Obstructive-Bowel) SICUT Collaborative Study Group, has reached a strong consensus agreement regarding the definition of the condition and the type of diagnosis (that should be clinical and radiological), as for the need of an admission to a surgical ward. In patients with uncomplicated obstruction, management could be conservative, including fluid and electrolyte replacement, intestinal decompression and bowel rest 32.
In this field, a smaller panel constituted by 13 international experts participated in the statement of the Bologna Guidelines for patients presenting with adhesive small bowel obstructions. Consistently with our consensus, Bologna guidelines reported that in absence of strangulation and history of persistent vomiting or CT scan signs of free fluid, mesenteric oedema, small bowel faeces sign and devascularized bowel, patients with can be managed safely with NOM and nasogastric tube decompression. Of note, according to the authors, NOM patients have shorter hospital stay, but present a higher recurrence rate and shorter time to readmission. Risk factors for recurrences are young age (<40 years) and matted adhesions. Open surgery is the preferred surgical treatment of strangulating small bowel adhesions as a first therapeutic option as well as after failed conservative management. In selected patients and with appropriate skills, laparoscopic approach can be attempted using open access technique 33. These guidelines have been updated in 2013, when panel experts discussed laparoscopic adhesiolysis as a procedure that could be attempted for first episodes of SBO and/or anticipated single band, given that a low threshold for open conversion should be maintained 34. Indeed, when SBO or LBO result in ischemia, perforation or peritonitis, emergency surgery is required 32. Recently, the World Society of Emergency Surgery conducted a systematic literature review for the evidences regarding the surgical management of LBO due to left colon cancer, highlighting also that literature in this field is relative poor and lacking of powered randomized controlled trials 35. According to their results, a Hartmann’s procedure should be preferred to loop colostomy (Grade 2B) and it should be the procedure of choice in patients with high surgical risk (Grade 2C) or in case of high risk of anastomotic dehiscence. Subtotal and total colectomy should be attempted when cecal perforation or in case of synchronous colonic neoplasm, since total colectomy is associated with higher rates of impaired bowel function (Grade 1A). On this basis, primary resection and anastomosis with manual decompression seems the procedure of choice 35. Nevertheless, in many cases, endoscopy may be useful for either establish a diagnosis and provide therapeutic options. Indeed, endoscopy can be used for bowel decompression, dilation of strictures or placement of selfexpandable metal stents either to restore the luminal flow as a final treatment or to allow for a delay until elective surgical therapy (bridge to surgery) 32. According to the review provided by the World Society of Emergency Surgery, colonic stents represent the best option when skills are available. Stents as a bridge to surgery seems associated with lower mortality rate, shorter hospital stay, and a lower colostomy formation rate (Grade 1B) 35. Stent placement has been further discussed by the European Society of Gastrointestinal Endoscopy (ESGE), who recommends that diagnostic evaluation of patients should always include a contrast-enhanced CT scan.
ESGE concludes that a prophylactic placement is not always recommended, but should be reserved for those patients presenting symptoms and CT evidences of malignant large-bowel obstruction, without signs of perforation; on the same extent also self-expandable metal stent as a bridge to surgery is not recommended as a standard treatment of occlusion due to left-sided colon cancers. For these patients, if potentially curable, a stent may be considered as an alternative to emergency surgery in those with increased risks (e.g. ASA 3 and/or age 70 years or more). Finally, according to the ESGE, a self-expandable metal stent should be considered the palliation of choice in malignant colonic occlusion with the exception of those treated with biologic antiangiogenic drugs.

Another fundamental principle of the clinical management of patients presenting intestinal obstruction is the water soluble contrast medium X-Ray (Gastrografin swallow) that could have with both diagnostic and therapeutic purposes. Gastrografin may be administered either orally or in via the naso-gastric tube both immediately at admission and after an initial attempt of conservative treatment of 48 hours. According to the Bologna Guidelines, and consistently with our consensus, the appearance of water-soluble contrast in the colon within 24 hours predicts resolution of the occlusion state; furthermore, its use in SBO is safe and reduces need for surgery, time to resolution and hospital stay. Also, in this field, a recent meta-analysis conducted on 14 randomized trial on patients with a diagnosis of SBO, concluded that gastrografin swallow is effective in predicting the need for surgery in patients with adhesive occlusions. In addition, it reduces the need of surgery and shorten the hospital stay.

Conclusions

This manuscript reports the consensus agreement of a panel of Italian surgical experts - on the behalf of the SICUT Society - covering the clinical and surgical management of patients presenting with SBO, LBO and pseudo-obstruction. Finally, it is important to remark that although this consensus is in line with current international strategies and previous published guidelines, the current study summarizes the agreement of a large panel of experts and were developed adhering to common clinical practices by using a well described methodology. Our findings could be useful tools in the daily management of these common and peculiar diseases, and moreover further studies are ongoing for establishing the exact timing of CT scan in SBO and the appropriateness of colonic stenting in a larger panel including radiologists and GI endoscopists.

References


Legend to the Figures

Figure 1. Delphi consensus round and study design.

Figure 2. Results provided by Delphi methodology. A. Graph bars showing agreement; B. Graph bars showing dis-agreement between panel members; C. Graph bars showing uncertain results.
**Figure 3.** Small bowel obstruction - clinical management flow-chart according to SICUT recommendations.

**Figure 4.** Large bowel obstruction - clinical management flow-chart according to SICUT recommendations.

**Appendix 1 – List of OBOW SICUT Collaborative group**