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TEXTILOMA OF THE ABDOMINAL CAVITY

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CONTENT

CONCEPTUAL LANDMARKS OF THE RESEARCH

Actuality and importance of the topic. Modern surgery involves working in a specific environment of the operating room with high levels of stress, pressure and risks accompanying complex technical procedures, as well as under conditions of significant time shortage [1]. A side effect of such intense activity is the constant threat of complications and medical errors [2]. Among the many potential complications, unintentionally leaving surgical objects in the operative field remains one of the most serious, and refers to the so-called "never events", i.e. that should not occur in any form, being completely preventable and caused exclusively by human errors [3]. However, they do occur, and descriptions of these events continue to appear in both the medical literature and the media press.

The most frequent (70-90%) they are textile foreign bodies (TFB) or "textiloma" [4], due to their common use in all surgeries, amorphous structure and variable size, shape and color, especially when the sponge is soaked with blood and becomes difficult to distinguish in the operative field [2, 5]. More than 50% of all incidents of remaining TFBs were recorded after abdominal surgery, due to the large volume and anatomical complexity of the abdominal and pelvic cavities [6]. The real incidence of abdominal textiloma is unknown and can hardly be accurately determined due to medical and legal issues. However, according to the most reliable estimates, the morbidity from abdominal textiloma is about one case in 1,000-1,500 abdominal surgeries [5, 7].

Textile objects retained in the abdominal cavity after surgery can cause various complications, sometimes extremely severe and even fatal [7, 8]. In addition to acute complications requiring urgent relaparotomy, the possibility of a foreign body is rarely considered in the diagnosis of an abdominal mass, leading to unnecessary examinations, invasive procedures, and radical surgeries [1, 9]. Theoretically, textiloma can be diagnosed using radiography, ultrasonography (USG), computed tomography (CT) and other imaging methods [10, 11]. However, the visual characteristics of abdominal TFB are not well defined and, due to the rarity of pathology, they are little known by a radiologist, that is why they are misinterpreted, and patients are often admitted with other competing diagnoses.

In addition to medical aspects, TFBs left in the abdominal cavity can have serious ethical and legal implications, leading to devastating consequences for the operating surgeon and medical institution [6]. Current ethical and legal norms require recognition, mandatory documentation and information of patient regarding TFBs retention, which implies additional explanations, some punishment of involved personnel, potential litigation and payment of all costs incurred as a result of the incident [2, 3]. Finally, cases of abdominal TFBs are generally underreported, due to the reluctance of clinicians and hospitals to disclose these types of errors [1, 11]. Therefore, the development and implementation of reliable and standardized safety methods is of primary importance, which should aim to eliminate or minimize accidental injury to patients during the time spent in the operating room, including erroneous retention of textile objects in the abdominal cavity [1, 3].

However, remain unclear the incidence of abdominal textiloma in daily practice of surgeons, as well as their theoretical competence and actual execution of the current ethical norms in occurrence of event. The specific clinical manifestations of abdominal textiloma and their dependence on interval of TFB retention, the type of individual response to a foreign body and

development of potential complications are not fully established. The risk factors that may contribute to retention of TFB in the abdomen, as well as the possibility of monitoring and managing them in order to reduce morbidity, have not been sufficiently identified. The comparative value of different diagnostic imaging methods has not been completely studied, while visual characteristics of abdominal textiloma and their relationship with clinical manifestations and patient history are not clear. The clinical scenarios for decision-making to remove the textiloma from the abdominal cavity, the optimal type and volume of surgical procedure, as well as the frequency and nature of postoperative complications were ultimately not determined. The role of individual, procedural and organizational errors in cases of abdominal TFB remains unclear, although it is indisputable that the development and strict adherence to preventive measures can improve the level of surgical patient safety.

Aim of study: To improve the accuracy of diagnosis and treatment results of abdominal textiloma based on identification of characteristic clinical and imaging manifestations, as well as the potential reduction of morbidity by developing and standardizing preventive measures.

Objectives of study:

1. Identification of suggestive clinical manifestations of abdominal textiloma and their dependence on the duration of retention, type of individual reaction to a foreign body, as well as the possible occurrence of complications.
2. Establishing significant risk factors for accidental retention of textile objects in the abdominal cavity during surgery, as well as possible measures for their control and management.
3. Determination of characteristic visual signs of abdominal textiloma, using different medical imaging methods, and assessment of their informative value.
4. Optimizing the indications and volume, and specifying the technical characteristics of surgical intervention for removal of abdominal TFB, as well as determining the particularities of postoperative period depending on type of textiloma and severity of intraoperative events.
5. Studying theoretical knowledge and real compliance by surgeons to the requirements of actual medical ethics regarding cases of unintentional retention of TFB in the abdominal cavity.
6. Development of the complex actions aimed at optimizing organizational and procedural measures in the operating room, and to prevent unintentional retention of TFB in the abdomen.

Methodology of scientific research

The present study comprised three components. The first part was a retrospective study, including 23 patients with confirmed abdominal TFB, and carried out simultaneously in two hospitals of Chisinau. The second part of study was based on retrospective evaluation of 15 primary histories of disease, and aimed to identify risk factors for TFB accidentally left in the abdominal cavity, the quality of patient safety measures in the operating room and their reflection in medical records. The third part was a cross-sectional observational study conducted through a voluntary, confidential and anonymous survey among 241 surgeons and obstetrician-gynecologists on various aspects of abdominal TFBs. The obtained qualitative and quantitative data were analyzed by statistical methods.

The novelty and scientific originality of obtained results

For the first time, results of diagnosis and treatment of 23 patients with textile objects unintentionally left in the abdominal cavity were assessed, which is one of the largest studies of abdominal TFBs published in medical literature within the last two decades.

For the first time, based on an anonymous and confidential survey, it was found that the majority (60.6%) of beginning surgeons and obstetrician-gynecologists from Moldova already have personal experience with retained abdominal TFB, and almost all (90.38%) with a professional career over 25 years, which confirms the notable incidence of event.

It has been proven that the risk of accidental retention of textile surgical objects in the abdomen does not depend on profile and resources of hospital and can occur in medical institutions of all levels and during any surgical procedure: general surgical (56.52%) and obstetric-gynecological (43.47%); performed with indications of immediate emergency (26.08%), delayed emergency (39.13%) and elected (34.78%); in district (34.78%), municipal (34.78%), and republican (21.73%) hospitals.

Based on analysis of clinical presentation of patients, it was proved the predominance of the threatening acute symptomatic (47.82%) and non-specific oligosymptomatic (43.47%) clinical variants of abdominal textiloma, while the asymptomatic course and the accidental recognition of TFB occurs only in minimum number (8.69%) of cases.

Based on comparative assessment of the medical imaging methods results, it was established that CT has the greatest diagnostic value (82.35%) regarding abdominal textiloma, which is much higher than USG ($p=0.001$) and plain or contrast radiography ($p=0.00001$).

For the first time, it was proven that transforming the CT-imaging characteristics of textiloma from type 1 to type 2 is completed after approximately 6 months, and consists in disappearance of air component, increase in density and decrease in volume of abdominal mass, thickening of capsule, followed by partial calcifications, due to specific response to sterile textile material and the constant pressure exerted by abdominal organs.

It has been established that the main microscopic histopathological signs of TFBs include the combination of chronic and acute inflammatory cell infiltration with the presence of large numbers of foreign body-type macrophage giant cells, granulomas, as well as deformed residual textile fibers. Nevertheless, macroscopically the chronic textiloma is usually represented by denatured textile material surrounded by a dense fibrous capsule.

It has been proven that the postoperative course after surgical extraction of abdominal TFB depends on process length and type of reaction to textiloma, and is the most severe in acute exudative form, accompanied by increased need for intravenous infusion (median value 8 days), antibiotic therapy (on average 12.58±10.59 days) and analgesics (on average 12.08±8.95 days), as well as longer hospital stay (median – 10.5 days).

For the first time it was shown, that even relatively short retention of gauze material in the abdominal cavity under certain conditions can lead to an unusually strong proliferative reaction of host organism to a foreign body and the formation of large abdominal granuloma, which can mimic a recurrent or new abdominal neoplasma.

For the first time were disclosed the discrepancy between official medical documentation and real data, and the dominant practice of deliberate concealment by operating surgeons of cases with detection and removal of TFBs left in abdomen, false description of imaging and intraoperative data, and replacement of true diagnosis with the alternative one.

It was established that 70% of surgeons and obstetrician-gynecologists of Moldova are not considered that the full blame for remaining abdominal TFB should be assumed only by operating surgeon, emphasizing the need to share the responsibility with operating nurse and whole surgical team.

The applicative value of study

It is appropriate to divide cases of abdominal textiloma into three groups according to severity of symptoms: acute symptomatic, oligosymptomatic and asymptomatic course, which allows a better specification of subjective and objective manifestations, establishing their connection with the previous laparotomy and determining the adequate curative policy.

In the absence of common national practice for marking of textile surgical objects, radiography remains uninformative, only in some cases presenting indirect and inconclusive signs, and cannot serve as a reliable method for diagnosis of abdominal textiloma.

It has been shown that USG signs suggestive of abdominal TFB include a hyperechoic anterior arch with intense posterior acoustic shadow, round mass with mixed cystic and solid content, or a well-circumscribed mass with cystic content and echogenic internal structures.

The curative decision based on USG data only, in case of textiloma is limited, taking into account the number of disadvantages, including often non-specific signs and inaccurate localization of abdominal mass, inadequate results in condition of paralytic ileus or abdominal tenderness due to local inflammation, and a large number of false-positive conclusions.

There are specified some characteristic tomographic findings of acute exudative (visualization of the clearly defined mass with soft tissue density and spiral texture or the spongy pattern with multiple gas bubbles inside), and chronic fibrinous (well-defined, round or oval mass, with a clearly defined capsule and solid internal density) forms of abdominal textiloma.

A retrospective evaluation of USG and CT protocols shows that radiologists often correctly visualize and describe the specific signs of an abdominal mass, but cannot recognize in it a textiloma, possibly due to lack of experience of how it might look like.

Surgical intervention for removing textiloma from the abdominal cavity should be performed as soon as possible after its diagnosis, in order to prevent the appearance of potentially life-threatening complications.

The repeated surgical procedure for removal of TFB from the abdomen should be performed in an open way, which is safer, allows complete exploration of abdominal cavity, safer extraction of textile objects, debridement and drainage of associated infected fluid collection, as well as solution of possible severe complications.

It was specified the choice of antibacterial remedies after repeated surgical procedure with the removal of abdominal textiloma, which in the acute exudative form should suppress bacteria of enteric group, and in the chronic fibrinous form with external purulent fistulas – to be active against nosocomial pathogenic microorganisms.

The need to create established rules and procedures for counting surgical objects in the operating room in each hospital, which are guaranteed to be known by all staff, has been shown. The document should specify when and by whom the count should be carried out, what objects should be counted and how to record the results of count, including those inconsistent or erroneous.

A standardized surgical safety protocol was developed and implemented in practice, which includes the multiple perioperative counting of gauze items, the preferential use during surgery of radiologically detectable objects, the limitation of sponges, the refusal to use small tampons, thorough exploration of surgical site before wound closure, effective communication between operating room staff and creating an optimal work environment.

Implementation of scientific results: Based on this study, the National Guide "Surgical patient safety in the operating room" was developed and approved by the Minister of Health of Moldova no.1226 of December 26, 2022. The document was addressed to reduce the risks of various iatrogenic complications, including abdominal textiloma. According to the accepted practice and following the instructions of the same order, all medical institutions in the country are obliged to develop their own institutional protocols based on this National Guide to optimize surgical safety and to follow their instructions closely.

Approval of scientific results. The results of research were reported and discussed at: 5th International Medical Congress for Students and Young Doctors "MedEspera", Chisinau, Moldova, 2014; "Severine Medical Days", The interdisciplinary conference with international participation. Drobeta Turnu Severin, Romania, 2014; The XXXVIth Meeting of surgeons from Moldova "Iacomi-Răzeșu", Piatra Neamț, Romania, 2014; XIIth Congress of the *Nicolae Anestiadi* Surgical Association, Chisinau, Moldova, 2015; 21 Annual Meeting of the European Society of Surgery (ESS), Krakow, Poland, 2017; The XIIIth Congress of the *Nicolae Anestiadi* Surgical Association and the IIIrd Congress of the Society of Endoscopy, Minimally Invasive Surgery and Ultrasonography, Chisinau, Moldova, 2019; National Congress of Surgery, 30th edition, Online event, Romania, 2020; 8th International Medical Congress for Students and Young Doctors "MedEspera", Chisinau, Moldova, 2020; The Congress devoted to the 75th anniversary of the founding of *Nicolae Testemitanu* SUMPh, Chisinau, Moldova, 2020; The annual conference of *Nicolae Testemitanu* SUMPh, Chisinau, Moldova, 2021; The Medical Days of Municipal Clinical Hospital "Saint Archangel Michael", Chisinau, Moldova, 2022; The XIVth Congress of the *Nicolae Anestiadi* Surgical Association and the IVth Congress of the Society of Endoscopy, Minimally Invasive Surgery and Ultrasonography, Chisinau, Moldova, 2023; The annual conference of *Nicolae Testemitanu* SUMPh, Chisinau, Moldova, 2023.

The results of the study were discussed and approved within: The meeting of the *Nicolae Anestiadi* Department of Surgery no.1, *Nicolae Testemitanu* SUMPh (minutes no.6 of 18.12.2023); Meeting of the Profile Scientific Seminar – 321.13. Surgery; 321.14. Pediatric surgery; 321.22. Urology and andrology, *Nicolae Testemitanu* SUMPh (minutes no.1 of 24.01.2024).

Publications on the thesis topic: 22 scientific papers were published, of which articles cited in SCOPUS/PubMed international journals – 1, articles in peer-reviewed international journals – 2, articles in national journals – 5, abstracts at international conferences abroad – 4, abstracts at international conferences in the republic – 3, abstracts at national conferences – 6, National Guidelines approved by the Ministry of Health of Moldova.

Summary of the thesis contents. The thesis includes the list of abbreviations, introduction, 5 chapters, synthesis, general conclusions, practical recommendations. Attached is the bibliographic index with 212 sources, appendices, the statement regarding the assumption of responsibility, the author's CV, 17 tables, 32 figures.

Key words: abdominal cavity, foreign bodies, textiloma, risk factors, ultrasonography, computed tomography, surgical treatment, medical ethics, iatrogenic complication, malpractice, surgical safety, prevention.

THESIS CONTENT

1. CURRENT STATUS OF THE ISSUE OF UNINTENTIONALLY RETAINED ABDOMINAL FOREIGN BODIES

The chapter presents a critical analysis of articles published in international medical literature regarding the problem of TFBs unintentionally left in the abdominal cavity. Data give the definitions, terminology used, and incidence of abdominal textiloma in historical and contemporary contexts, including analysis of the reasons for their underreporting. Next, the natural history of TFB left in the abdomen and the types of host organism response to a foreign body are described in detail. A brief review of published papers is made concerning the number of cases, volume of surgical procedures and time interval of abdominal textiloma's retention.

2. CLINICAL DATA AND RESEARCH METHODS

2.1. Design and general characteristics of study components

The present study included three component parts with different design and methodology (figure 1). Design and protocol of the study were approved by Ethics Committee of *Nicolae Testemitanu* SUMPh (minute no.48 of 12.02.2020). The first part was based on a retrospective analysis, carried out simultaneously in two hospitals in Chisinau: Institute of Emergency Medicine and *Gheorghe Paladi* Municipal Clinical Hospital, which are the clinical bases of *Nicolae Anestiadi* Department of Surgery no.1 and of Department of General Surgery and Semiology no.3, *Nicolae Testemitanu* SUMPh.

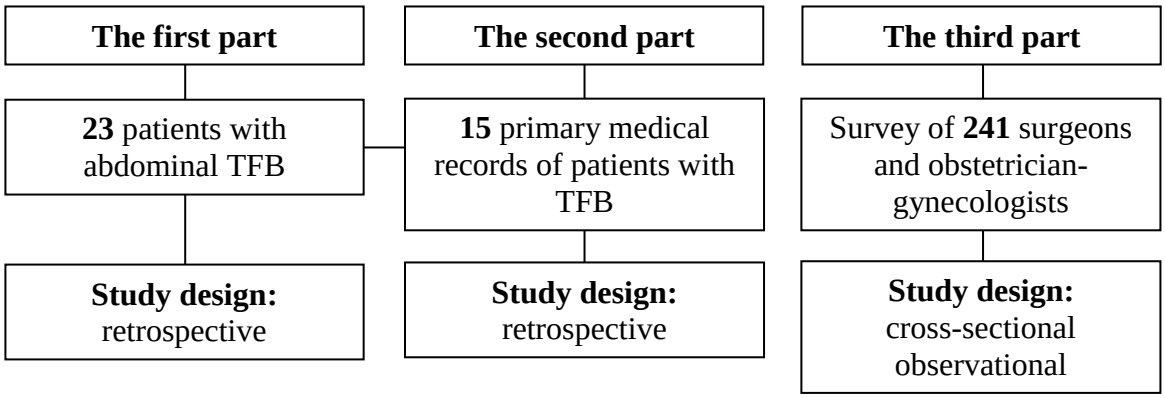

Figure 1. **Diagram representing three components of the study and their design**

In the **first part of study**, 23 cases of abdominal TFB were identified over a 15-year period. The following data were collected: gender and age of patients; type, urgency, and other features of primary surgery in which TFB was left in the abdomen; preliminary diagnosis before detection of textiloma; time interval from the causative surgery to discovery of TFB; clinical manifestations; diagnostic approaches and examinations results; the circumstances and methods of textiloma extraction; intraoperative findings, volume of reoperations, and postoperative complications. Also, the quality of medical documentation was analyzed, paying special attention to information disclosure regarding detection of textile surgical objects. The principle of confidentiality concerning patients' personal data was kept strictly.

From 23 patients enrolled in the study, majority were women – 16 (69.56%). The age of patients at time of primary laparotomy ranged from 5 to 74 years and was on average 37.48±16.5 years (95% CI 30.34-44.61). At the time of TFB diagnosis and extraction, the age of patients

varied between 20 and 74 years and was on average 40.26±15.29 years (95% CI 33.65-46.87). The median age of women was significantly lower, 35.69±14.95 years (95% CI 27.72-43.65), compared to 50.71±10.72 years (95% CI 40.8-60.63) in men, ($p < 0.01$, Mann-Whitney test).

All primary surgeries when TFBs were retained in the abdominal cavity were opened (table 1). Obstetrical or gynecological procedures were performed in 10 (43.47%) patients, while interventions for surgical pathology – in 13 (56.52%) patients. Primary surgical interventions were carried out as an immediate emergency in 6 (26.08%) patients, delayed emergency – in 9 (39.13%) and elected – in 8 (34.78%) patients. Nonetheless, primary surgical intervention in 8 (34.78%) cases were performed in district hospitals, in 8 (34.78%) – in municipal hospitals, in 5 (21.73%) – in republican hospitals, and in the remaining 2 (8.69%) cases – in another country. In total, primary causative surgeries were performed in operating rooms at 11 different medical institutions. Thus, the risk of TFB being left in the abdomen exists in hospitals of all levels, regardless of their profile and resources.

Table 1. **Demographic characteristics and surgical history of patients**

No.	Gender, age (years)	Primary surgery	Interval until TFB diagnosis (days / months / years)
1	F, 29	Cesarean section for mature pregnancy	24 days
2	F, 28	Incisional hernioplasty	243 days / 5 months
3	M, 52	Inguinal hernioplasty	1957 days / 5,5 years
4	F, 27	Parametric hematoma drainage	5 days
5	F, 26	Tubectomy for ectopic pregnancy	60 days / 2 months
6	M, 32	Laparotomy for penetrating abdominal wound	2920 days / 8 years
7	M, 60	Right hemicolectomy for intestinal obstruction	46 days / 1,5 months
8	F, 54	Open cholecystectomy for acute cholecystitis	119 days / 4 months
9	F, 32	Tubectomy for ectopic pregnancy	165 days / 5,5 months
10	F, 50	Hysterectomy for uterine myoma	6570 days / 18 years
11	F, 21	Cesarean section for mature pregnancy	5 days
12	F, 24	Left hemicolectomy for dolichosigma	76 days / 2,5 months
13	M, 60	Hartmann procedure for intestinal obstruction	16 days
14	F, 35	Cesarean section for mature pregnancy	153 days /5 months
15	F, 29	Ovarian cystectomy for endometrioid cystoma	2160 days / 6 years
16	F, 20	Spleno-renal shunt for portal hypertension	5840 days / 16 years
17	M, 54	Gastrotomy, hemostatic oversewing of gastric ulcer	13 days
18	F, 74	Duodenotomy, hemostatic oversewing duodenal ulcer	96 days / 3 months
19	M, 57	Distal gastric resection for bulbar stenosis	16 days
20	F, 26	Cesarean section for placental abruption	1 day
21	F, 51	Open cholecystectomy for acute cholecystitis	150 days / 5 months
22	F, 45	Total hysterectomy	1460 days / 4 years
23	M, 40	Appendectomy	1194 days / 3,5 years

The intraperitoneal retantion of surgical sponge varied widely, from one day to 18 years, and in median was 119 (25%-75% IQR 16-1460) days. The longest duration of disease in present study in two cases reached 16 and 18 years, respectively.

The patients of the study group were divided into two subgroups according to the type of foreign body response: (1) **Acute exudative** (AE) form, and (2) **Chronic fibrinous** (CF) form. As a result, the group with AE form of TFB included 12 (52.17%) patients (cases no.1, 4, 5, 7, 11, 12, 13, 14, 17, 18, 19, 20), and the group with CF form – 11 (47.82%) patients (cases no.2, 3, 6, 8, 9, 10, 15, 16, 21, 22, 23). Apart from the main groups, a subgroup of 5 (21.73%) patients (cases no.5, 6, 8, 9, 12) with digestive fistulas, formed due to TFB, was considered.

The second part of the study aimed to identify all circumstances and possible risk factors, which contribute to unintentionally leaving TFB in the abdominal cavity. For this purpose, medical records describing primary surgical intervention were analyzed retrospectively. In addition to medical aspects and identification of the presumed risk factors, attention was paid to the evaluation of patient safety measures in the operating room, as well as their reflection in medical documentation. In total, 15 (65.21%) medical records were evaluated.

The third part included a cross-sectional observational study organized by survey sent as a questionnaire to surgeons and obstetrician-gynecologists. Responses were voluntary, confidential and anonymous. No information was collected to establish the doctor's exact identity and workplace. The questions can be divided into four parts. The first part included information about the doctor's surgical specialty and seniority, as well as the type of hospital he works in. The second part contained questions about personal experience with abdominal TFBs. In the third part, the contributing factors and existing and potential theoretical measures to prevent TFB retention were evaluated. In the last fourth, most numerous part of questions focused on how doctors view and approach the ethical and legal issues associated with the retained TFB. Majority of 241 respondents were general surgeons – 143 (59.33%), gynecologists and obstetricians – 64 (26.55%). The remaining 34 (14.10%) participants represented other surgical specialties. 114 (47.30%) carried out their professional activity in republican institutions, 50 (20.74%) – in municipal hospitals, 61 (25.31%) – in district hospitals and another 16 (6.63%) – in departmental or private hospitals. The length of respondent's practice was up to 5 years at 33 (13.69%), 5-15 years at 54 (22.40%), 15-25 years at 55 (22.82%), 25-35 years – at 52 (21.57%) and over 35 years – at 47 (19.50%).

2.2. Research methods

Bibliographic resource work included a comprehensive review of published cases of abdominal foreign bodies by searching the electronic databases PubMed, Google Search, Google Scholar, Scopus and Web of Science between the years 2000 and 2023. Older publications were concerned if they contained relevant data. Search terms included "foreign bodies", "foreign surgical objects", "retained surgical objects", "textiloma", "gossypiboma", "corpus alienum", "gauzoma", and "muslinoma". No language restrictions applied.

The examination of patients with suspected retained abdominal TFB, aside of physical methods and routine laboratory tests, included imaging, bacteriological and histological studies.

Plain abdominal radiography was performed in 10 (43.47%) patients, while contrasted radiographic methods – in 6 (26.08%) patients.

Abdominal ultrasound, often multiple, was performed in 21 (91.30%) patients from the study group. Textiloma was considered sonographically as a well-defined mass containing an undulating internal echogenic focus with a hypoechoic border and a posterior acoustic shadow [12, 13]. The classification of Q.Y.Li [10] was used, which divides ultrasound images of TFB into three types: (1) Hyperechoic area or anterior echogenic arch with strong posterior acoustic

shadow and visible hypoechoic capsule; (2) Nonspecific pattern showing mixed cystic and solid internal content and/or hypoechoic mass; (3) Well-circumscribed mass with cystic content and undulating or zigzag "floating" echogenic internal structures [12, 13].

Multislice CT scanning was performed in 17 (73.91%) patients. Two main types of TFB visual appearance were considered: (1) "Acute" textilomas are presented by the well-circumscribed mass with a spongy pattern, with gas bubbles inside [1, 14]; (2) In case of "chronic" textiloma, it presents as a well-demarcated round or oval mass with a clear-defined capsule, a high density of internal structures, or a complex mixed signal pattern [14].

Upper endoscopy was used in a single (4.34%) case for diagnosis and removal of abdominal TFB. Laparoscopic diagnosis of textiloma was performed in 3 (13.04%) patients.

Based on the obtained data and description of examination protocols, their results were divided into three groups: (1) "Diagnostic", i.e. proper visual signs of abdominal TFB, (2) "Suggestive", i.e. visual findings of a possible TFB, (3) "Non-informative", in case of its inconclusive or false results.

The data extracted from medical records of patients with abdominal TFB were introduced into a database in Microsoft Excel and submitted to statistical analysis, using GraphPad Prism 5.0 software and MedCalc Software Ltd. In the thesis the data are presented as absolute and relative values, mean values with standard deviation and 95% confidence interval, or median with 25%-75% interquartile range. The normality of data distribution was assessed using the Shapiro-Wilk test, applying parametric and non-parametric statistical methods for further analysis. The unpaired one-tailed t-test with Welch's correction or the Mann-Whitney test was used to compare means, and the Fisher exact test was used to compare proportions. p values <0.05 were considered the threshold of statistical significance.

3. CLINICAL AND INSTRUMENTAL DIAGNOSIS OF ABDOMINAL TEXTILOMA

3.1. Variability and non-specificity of clinical data in abdominal TFB

The main symptoms in patients with abdominal TFB were: abdominal pain (82.60%), low or high fever (52.17%), intestinal dysfunction (34.78%), local sensitivity and tenderness (34.78%) and palpable abdominal mass (30.43%). In addition, patients with TFB presented a wide range of complaints, including asthenia, weakness, anorexia, recurrent nausea and vomiting, constipation and diarrhea, vague abdominal heaviness and discomfort, weight loss, chronic purulent fistula with opening in postoperative scar and others. Only 2 (8.69%) patients had no symptoms at the time of accidental detection of abdominal TFB.

However, a comparison of clinical manifestations severity between subgroups revealed some differences. Thus, sudden pain as a symptom of "acute abdomen" was noted significantly more often in the group with AE form of TFB (41.66% vs 18.18% in the CF form). Hectic fever above 38°C was observed exclusively in patients with AE form of TFB (41.66% vs 0% in CF form, $p < 0,05$, Fisher test). Also, other alarming symptoms were significantly more frequently observed in the group of patients with AE form compared to CF form of TFB, including abdominal muscle defense (58.33% vs 9.09%, respectively, $p < 0.05$, Fisher test), peritoneal irritation (58.33% vs 0%), intestinal paresis and dysfunction up to acute obstruction (50.0% vs 18.18%). More intense clinical manifestations required urgent admission in 6 patients with the AE form of abdominal TFB, and in another 4 patients "acute abdomen" developed in the early postoperative period, during the same hospitalization. In contrast, only 4 (36.36%) patients with CF type of TFB were

urgently hospitalized ($p < 0.05$ Fisher test, compared to the AE group). The median time since primary surgery in the group of patients with AE form was 20 (25%-75% IQR 7-72) days (from 1 to 153 days) and was significantly longer in the group of patients with CF form: 1460 (25%-75% IQR 150-2920) days (from 119 to 6570 days or 18 years), $p < 0.0001$ (Mann-Whitney test).

Except for two patients, in whom the textiloma was discovered incidentally on imaging studies, all others were symptomatic. However, the clinical presentation of abdominal textiloma was extremely diverse, and the symptoms of disease were so numerous, variable, and mostly nonspecific that establishing an accurate diagnosis based on physical symptoms alone was extremely difficult. Summarizing the mentioned data, it is possible to classify the cases in our series into three groups according to severity of clinical manifestations:

- **Asymptomatic evolution** (accidental recognition during routine imaging examination) – 2 (8.69%) cases (no.3, 16);
- **Oligosymptomatic evolution** (non-specific and moderate symptoms, more characteristic of chronic pathology) – 10 (43.47%) cases (no.1, 2, 8, 9, 10, 14, 15, 18, 21, 22), although in 4 cases – in association with palpable intra-abdominal mass;
- **Severe/acute evolution** (marked alarming symptoms, characteristic of acute conditions – 11 (47.82%) cases, including: symptoms of abdominal abscess with systemic febrile reaction – 6 (no.4, 5, 7, 11, 13, 19), acute intestinal obstruction – 2 (no.12, 23), intra-abdominal hemorrhage – one case (no.20), gastric bleeding – 2 cases (no.6, 17).

Thus, the clinical presentation of abdominal textiloma is very variable and non-specific in both types of response to a foreign body. Symptoms due to abdominal TFB may appear in the first days or many years after the causative surgical intervention. As a rule, the retention of a textile object is rarely considered in abnormal course of postoperative period. Therefore, the subjective and objective symptoms of abdominal textiloma are often interpreted by clinicians as a manifestation of common inflammatory postoperative complications (in AE form) or of a new tumor (in CF form). The timely diagnosis of abdominal TFBs is difficult and requires a thorough analysis of the patient's complaints, data of physical examination, surgical history and a high index of suspicion.

3.2. Assessment of risk factors for unintentional retention of TFB in the abdomen

Identification of risk factors for unintentional intra-abdominal retention of textile surgical objects may lead to elimination or significant reduction of these errors and to improvement of surgical patient's safety. TFBs retention was recorded after urgent surgeries in two thirds of cases (65.21%). In 60.0% of cases, the surgical procedure was long, over 1.5 hours, and in 4 cases the length of operation exceeded 2 hours. In 4 (26.66%) cases, the surgery was performed after the end of regulated "working hours", i.e. after 17:00. Significant blood loss was found in 63.63% of patients. The highest blood loss was 1200 mL in an emergency cesarean section for placental abruption and fetal death (case no.20).

The present study could not assess the impact of most risk factors associated with organization and communication in the operating room on CST retention. No indication of disorganization, inadequate working conditions and excessive fatigue, poor communication or hierarchical nature of surgical staff was found in surgical protocols. In two cases the change of scrub nurse during the procedure was indicated. Both surgeries were segmental colon resections, one – urgent (case no.13), the other – elective (case no.12), performed in the late "after-working" hours, accompanied by replacing the "day" nurse with the "on-duty" one.

However, the fact of counting textile pads before closing surgical site was reflected in only 2 (13.33%) of 15 available protocols, and exploration of the abdominal cavity to detect foreign bodies – in only 3 (20.0%). Even if counting of sponges and abdominal exploration were indeed performed, the lack of documentation of these processes formally suggests otherwise, which is at least evidence of disorganization in the operating room and violation of surgical safety standards.

Thus, the risk factors for forgotten abdominal TFB include an emergency operation, its major duration and significant blood loss, change of scrub nurse, as well as the lack of documentation and possibly real counting of textile objects and complete exploration of abdominal cavity before closing the surgical wound.

3.3. Laboratory and imaging diagnosis of abdominal textiloma

Although the suspicion of abdominal textiloma should arise after a careful assessment of subjective and objective symptoms and a thorough analysis of the patient's surgical history, the definitive diagnosis is unbelievable without the use of modern instrumental diagnostic tools.

Plain abdominal radiography was performed in 10 (43.47%) patients with textiloma and was not diagnostic in any case. Radiological studies with contrast were performed in 6 (26.08%) patients with TFB, and were diagnostic in one (16.66%) case, suggestive – in 2 (33.33%) and non-informative – in 3 (50.0%).

Proper visual signs of textiloma at abdominal USG were recorded in 6 (28.57%) cases; echographic images suggestive of TFB – in 5 (23.80%); and the exam was uninformative – in 10 (47.61%). Among patients with relevant results, USG image of type 1 textiloma was established in 5 (23.80%) cases, type 2 – in 2 (9.52%), and type 3 – in 7 (33.33%). In addition, ultrasound visualization of type 1 and 2 abdominal mass was characteristic for AE form of TFB – 5 (71.42%) of 7 cases (figure 2). Instead, type 3 was determined almost exclusively in CF forms – 6 (85.71%) out of 7 cases. The mean sizes of abdominal lesions, when indicated in the USG report, were 91.56±35.18 mm (larger size) and 71.22±21.56 mm (smaller size). Although the evaluation of obtained data confirms that transabdominal USG can attest or with high probability suspect the TFB in more than half of cases, ultrasound examiners often correctly visualize the abdominal mass, but cannot recognize it as textiloma.

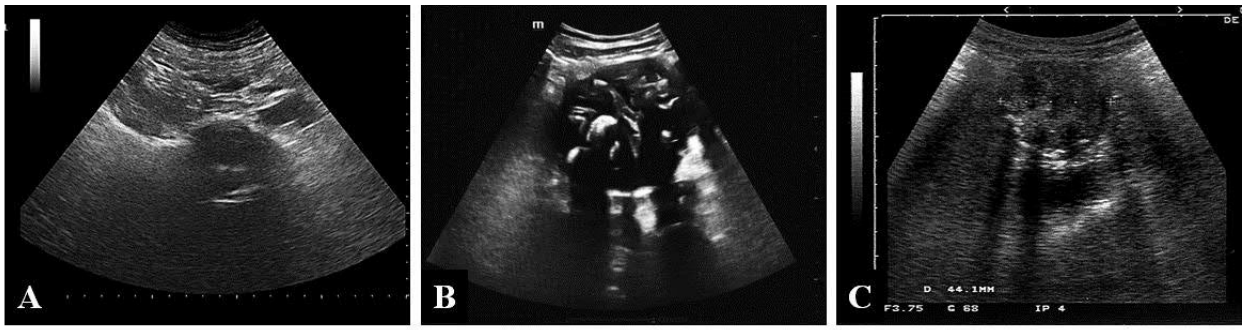

Figure 2. **Different ultrasound types of abdominal TFB in the study group**
(A) Case no.7: Hyperechoic arch outlining a foreign body with posterior acoustic shadow – type 1; (B) Case no.23: Cystic mass with multiple internal echogenic structures chaotically arranged – type 2; (C) Case no.16: Well-circumscribed rounded mass with dense content and foci of calcification – type 3.

Abdominal CT was performed in 73.91% patients with TFB, and was used with similar frequency in AE and CF forms: 75.0% vs 72.72%. These studies were diagnostic and reliably detected abdominal textiloma in 14 (82.35%) cases and raised strong suspicions of TFB – in the remaining 3 (17.64%), but in all of them upon retrospective evaluation of archived images. The

most typical location of abdominal TFB was the mesogastric area – 7 (41.17%), followed by pelvic cavity – 4 (23.52%), the right or left iliac fossa – 2 (11.76%), the epigastric region – 2 (11.76%), and left subphrenic and right subhepatic spaces – one (5.88%) case each. The abdominal mass had a regular oval or round shape in 16 (94.11%) observations. According to CT characteristics, textilomas corresponded to type 1 in 10 (58.82%) patients, and to type 2 – in 7 (41.17%) patients (figure 3). In patients with the AE form, type 1 imaging was established in all 9 (100%) cases. On the contrary, in patients with the CF form of TFB type 2 CT prevailed statistically significantly: in 7 (87.5%) of 8 observations ($p < 0.001$, Fisher test). Also, a statistically significant difference was noted regarding the duration of TFB retention in the abdominal cavity, depending on the type of CT images. Thus, in type 1 it was 50.50±51.15 days, and in type 2 – 2720.0±2582 days, or more than 7 years ($p < 0.01$, *t* test).

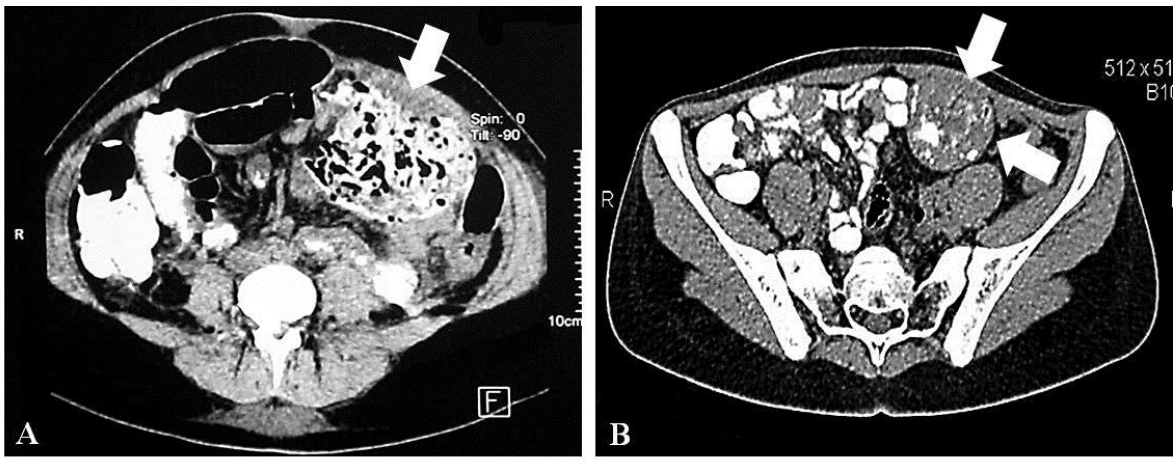

Figure 3. **Acute and chronic types of abdominal textiloma on CT**
(A) Case no.4: Axial CT demonstrates a massive conglomerate with a fine capsule and multiple air bubbles, measuring 120x108x88 mm (arrow) – type 1; (B) Case no.16: Axial CT with intraluminal contrast reveals a 52x50x46 mm bulky, rounded mass in the left iliac area, with solid organ-like density and "mottled" visual appearance due to focal calcification (arrows) – type 2.

Therefore, the CT scan in the present study demonstrated a high efficiency, with diagnostic value approaching 100%, and proved to be able to accurately localize the textiloma, its sizes and the relations with surrounding organs and structures. In addition, abdominal CT is a practical tool for recognition of textiloma both in acute symptomatic cases and in chronic asymptomatic or oligosymptomatic ones.

Secondary visual findings of abdominal textiloma on CT scan, correlated with clinical manifestations and anamnestic data could be of major scientific and practical importance. The average volume of type 1 textilomas was 548.33±388.3 mm3, and it proved to be statistically significantly lower in the case of TFB type 2 – 120.08±39.36 mm3 ($p=0.01$, *t* test). In the vast majority of cases, the abdominal mass was surrounded by a capsule, with a median thickness of 4.35 (25%-75% IQR 1.62–9.0) mm (range 1 to 15 mm) and showing marked enhancement on postcontrast studies. Another characteristic of textiloma type 1 on CT is the visualization of multiple air bubbles within the abdominal mass, associated with the capture and retention of air between the textile fibers [14]. In this study, the air or air-fluid density of mass was established in 11 (64.70%) of 17 cases. Notably, in all these cases the intraperitoneal duration of TFB varied between 1 and 165 days, that is, it did not exceed 5.5 months. In contrast, cases with masses of airless solid internal density were characterized by a long-standing abdominal TFB. As a result,

if the textiloma does not cause an acute response reaction, remains sterile and is not diagnosed early, the gas bubbles inside the TFB are gradually absorbed and disappear. According to presented data, the process of disappearance of air components from textiloma is completed after approximately 6 months, and from the point of view of CT-imaging, the textiloma transforms from a type 1 to a type 2. The decrease in the volume of textile material over time should be related to the constant and prolonged pressure exerted by abdominal organs on TFB, which eventually leads to the formation of a dense, well-circumscribed, round or oval mass of relatively small size.

A special problem was determination of CT scan value in case of hollow viscus erosion and fistula. In the present series, fistulization was established in 5 (21.73%) cases: stomach (no.6, 8), small intestine (no.12), and colon (no.5, 9). Definite visual signs of fistula were detected and indicated by radiologist in 2 cases with colonic lesions (figure 4).

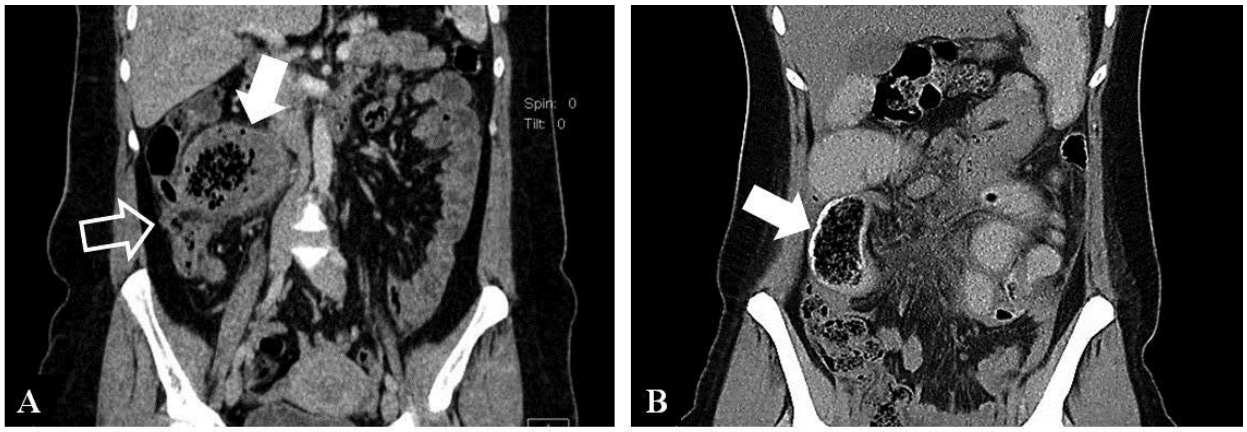

Figure 4. **CT diagnosis of the hollow organs fistula, caused by textiloma**
(A) Case no.9: Coronal CT reveals a 74x98x72 mm air-fluid density textiloma in the right mesogastric region (arrow) with fistulization of ascending colon (open arrow); (B) Case no.12: Coronal abdominal CT with intraluminal contrast revealed a marked distention of jejunal loop, ending blindly in the right mesogastric and containing an indistinct mass with hyperdense walls up to +200 UH – textiloma completely migrated into the intestinal lumen, covered by a layer of barium (arrow).

In 6 patients abdominal textiloma was diagnosed in an alternative way, without CT: 4 TFB were accidentally discovered during open surgeries performed for complications of unrecognized foreign bodies: (1) Postoperative peritonitis and paralytic ileus (case no.11); (2) Chronic purulent fistula of postoperative scar, with uninformative USG and fistulography (case no.14); (3) Repeated massive bleeding from gastric Dieulafoy lesion (case no.17); (4) Acute bowel obstruction (case no.23). In one patient (case no.15) abdominal TFB was discovered during laparoscopic surgery for an ovarian “cyst”. The last observation (case no.8) is an example of a rare textiloma diagnosis by endoscopic methods.

3.4. Comparative informative value of medical imaging methods in TFB

Textile material accidentally left in the abdomen potential can be diagnosed by conventional and contrast radiological studies, USG and CT. However, the visual presentations of textiloma are very heterogeneous and depend on the interval of TFB retention, its location and the presence of complications. The comparative informative value of the main diagnostic methods for detection of abdominal textiloma, according to study results, are presented in figure 5.

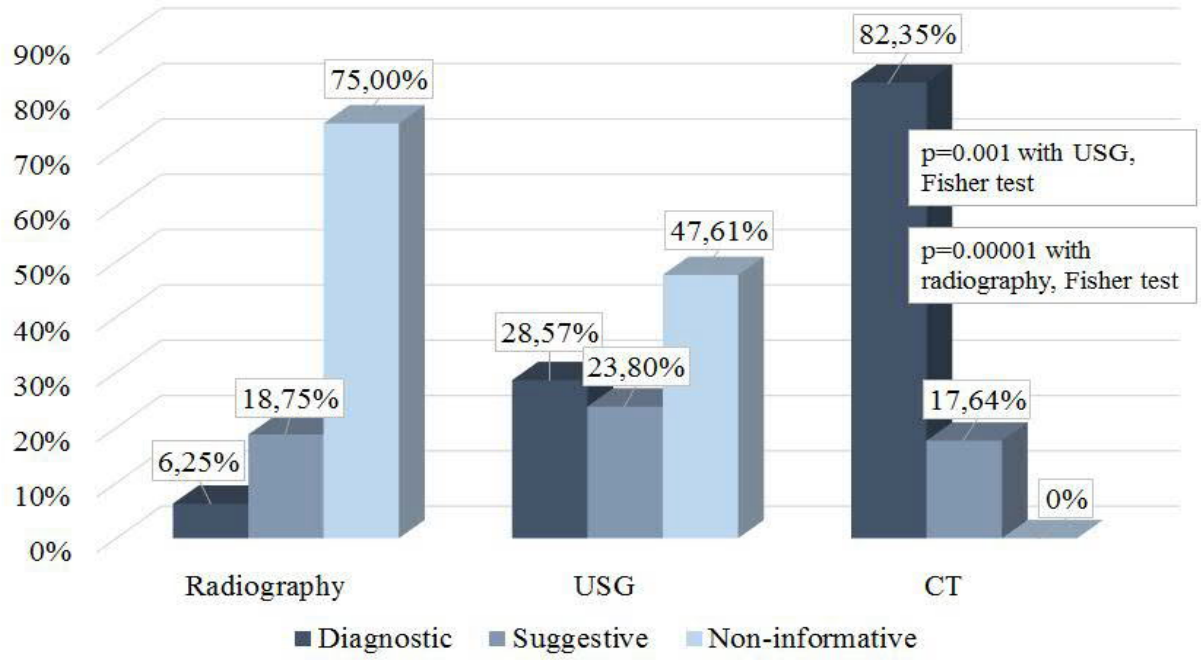

Figure 5. **Comparative diagnostic value of imaging studies in abdominal TFB**

Thus, the radiological methods proved to be the least informative, primarily due to the absence of surgical sponges with radiopaque markers in the operating rooms of Moldova. Unique cases of abdominal TFB were identificated only with the use of contrast techniques. Despite its high ability to detect abdominal textiloma, USG has many limitations, including a high false results rate, inability to localize TFBs and their anatomical relationships, and operator dependence. In the study, CT was shown to be a most reliable diagnostic method for retained abdominal TFBs with a positive diagnostic value of 82.35% and complete absence of non-informative results. Additional advantages of CT compared to USG are: objective and available for repeated evaluation results, ability to accurately establish location, size, and anatomical relationship of TFB, and detection of less common complications, such as digestive fistula and transmural migration of textile objects.

4. TEXTILOMAS' REMOVAL FROM THE ABDOMINAL CAVITY

4.1. Decision-making scenarios for the TFB removal surgery

The wide variability of clinical manifestations, surgical history and imaging data at the time of repeated patients' presentation led to a large number of decision-making scenarios for the removal of retained abdominal textile objects. The preoperative diagnosis of abdominal TFB is not always certain, preliminary imaging data are controversial or misleading, while acute clinical conditions often limit time and opportunity to complete patients' examination. Thus, three main decision-making scenarios regarding surgery to remove TFB from the abdomen can be highlighted:

(1) **Early detection** – 4 (17.39%) patients (cases no.4, 13, 19, 20), who at the time of TFBs diagnosis were still hospitalized after primary surgery. All patients in the early postoperative period were examined by abdominal CT with confirmation of diagnosis and underwent a relaparotomy.

(2) **Delayed detection** – the most heterogeneous group, including 10 (43.47%) readmitted

patients with a wide range of clinical manifestations, usually due to abdominal textiloma. Of these, in 4 patients TFB was diagnosed on preoperative CT (cases no.5, 7, 9, 18), followed by urgent relaparotomy. In another patient, CT revealed marked pathological changes, but no evident correlation with TFB (case no.6), and sponge was discovered only on examination of removed specimen. In the other 4 patients (cases no.11, 12, 17, 23), urgent surgery was indicated in connection with acute surgical conditions (intestinal obstruction, peritonitis and upper digestive bleeding). In all cases, the textiloma was diagnosed during laparotomy. The separate case represents detection and endoscopic extraction of abdominal TFB (case no.8).

(3) **Late detection** – a group of 9 (39.13%) asymptomatic or oligosymptomatic patients, in whom abdominal TFB was suspected following imaging investigations performed in out-hospital settings, with subsequent scheduled admission. The majority (77.77%) had the CF form of TFB, and the median intraabdominal retention of textile material was 1460 (25%-75% IQR 146.5-4000) days, which is higher than in cases with delayed and early detection of TFB: 86 (25%-75% IQR 37.75-422.3) days and 10.5 (25%-75% IQR 2-16) days, respectively ($p < 0.05$, Mann-Whitney test). Six patients in this group had supporting USG or CT findings and underwent elective reoperation (cases no.1, 2, 10, 16, 21, 22). The remaining 3 patients were readmitted with alternative diagnosis, and textiloma was detected only intraoperatively.

Summarizing the presented data, the results of preoperative imaging studies (including CT, USG, X-ray and endoscopy) served as an indication for surgery to remove textiloma in only 15 (65.21%) cases. In the remaining 8 (34.78%) patients, indications for surgical intervention were presented by various acute clinical conditions or the need to clarify origin of unclear abdominal masses. Consequently, TFB was disclosed during surgery in 6 (26.08%) cases, and in 2 (8.69%) – it became evident only on gross pathological examination of removed abdominal mass, that is their discovery was largely an intraoperative or even postoperative finding.

4.2. Feauters of surgical intervention for removal of the abdominal textiloma

Removal of TFBs inadvertently left in abdominal cavity required repeated surgical interventions in the vast majority (95.65%) of cases. The only observation (case no.8) of endoscopic extraction of textiloma that caused erosion of the gastric wall is rather an exception.

The repeated surgery was performed in urgent settings in 12 (54.54%) cases and elected – in 10 (45.45%). However, patients with the AE form of TFB underwent urgent surgery much more frequently due to occurrence of acute abdominal complications than patients with the CF form, which often imitated abdominal tumors (75.0% vs 30.0%, $p=0,08$, Fisher test), although the trend did not reach the level of statistical significance. Generally, the comparison of intraoperative data in the groups of patients with AE and CF forms of abdominal textiloma leads to surprising conclusions. Although the level of semi-quantitative preoperative parameters, which evaluate the urgency and risk of surgery, except for microbial contamination class ($p=0.03$, Fisher test), had a tendency to be higher in patients with the AE form of TFB, the operative procedure itself was slightly longer and accompanied by a higher number of unexpected adverse events in the group of patients with CF textiloma. In other words, surgery to remove chronic abdominal textiloma may present significant and unexpected technical difficulties due to more severe anatomical changes, despite often oligosymptomatic clinical manifestations.

In 14 (63.63%) patients, the volume of surgical intervention was limited to simple extraction of TFB, accompanied by cleaning of residual cavity and confirmation of the adjacent anatomical structures integrity. In one case this volume was completed by appendectomy (case no.10), and

in the other case – by salpingostomy (case no.15), due to involvement of these structures in the inflammatory infiltrate. In 4 (18.18%) patients, enucleation of encapsulated chronic textiloma was performed, in two cases completed by the imposed omental resection.

More extensive surgical procedures were required in 4 (18.18%) cases. In one of these (case no.9), TFB caused necrosis and fistula of sigmoid colon, necessitating closure defect. In another patient (case no.11), the local inflammatory process due to TFB led to the need for total hysterectomy. In case no.12, the textiloma migrated completely into the jejunal lumen, causing intestinal obstruction. And one young patient (case no.6) underwent subtotal gastric resection for an inflammatory tumor mimicked by intraparietal incorporation of TFB.

In the present study, 5 cases of erosion and fistulization of hollow viscus were confirmed, including stomach, colon and small intestine. The occurrence of cavitary organ fistula significantly worsens the technical execution of TFB removal procedures, increases its volume and the risk of intra- and postoperative complications. Thus, comparison of the same intraoperative parameters between subgroup of patients with (n=4) and without (n=18) fistulas demonstrates the following results: the degree of microbial contamination of surgery >2 was 75.0% in the subgroup with fistula and 27.77% – in the group without this complication ($p > 0.05$); severity of intraoperative events ClassIntra >I – 100% vs 22.22%, respectively ($p < 0.01$, Fisher test); and the length of surgery – 161.3±99.36 min vs 70.56±38.23 min, respectively ($p < 0.01$, *t* test).

Therefore, open surgery is the safest method of removing TFB from the abdominal cavity. Although simple extraction of TFBs by exploratory laparotomy was the most common procedure in the present study (81.81%), even such a surgery could have unwaiting consequences. In four cases or in almost every fifth patient, the pathological changes caused by abdominal TFB required primary repair or extensive resection of the damaged organs.

4.3. Histopathological and bacteriological characteristics of textiloma

According to current surgical practice, any tissue obtained during surgery is subjected to histopathological examination. Whereas, it is not clear whether this rule applies to textile foreign bodies. In common surgical practice in Moldova, the extracted sponge is photographed for the "personal archive" of the surgeon, but more often the removed TFB is hidden, and information about it does not go beyond the operating room.

However, in a textiloma of chronic type, a pseudotumor formed by TFB and surrounded by a fibrous capsule or a resected tissue is examined macro- and microscopically, which was performed in 8 (34.78%) cases in this clinical series. The macroscopic appearance of chronic textiloma showed a whitish round or oval mass with hard consistency, uneven surface and variable size. The thickness of the capsule was up to 10 mm, with isolated areas of calcification. Inside the mass was a conglomerate of disorganized and partially denatured textile fibers, without fluid components and signs of inflammation (figure 6).

Microscopic examination revealed the presence of granulation tissue and fibrous wall around the TFB. The main histopathological findings included the association of chronic and acute inflammatory cell infiltration, fibrosis in various degrees of distribution and maturation, focal necrosis and degenerative aggregation of leukocytes. The main distinguishing features of TFB are the presence of macrophageal giant cells of "foreign body" type, granulomas, as well as the visualization of residual textile fibers (figure 7). The latter are determined as straight or twisted fragmentary bands of white color, often highly distorted.

Figure 6. **Photographs of gross pathologic specimen of chronic abdominal textilomas**
Disorganized and partially denatured textile fibers surrounded by a thick fibrous capsule are observed in the specimens. (A) Case no.3: length of intraabdominal retention 5.5 years; (B) Case no.16: length of retention 16 years; (C) Case no.23: length of retention 3.5 years.

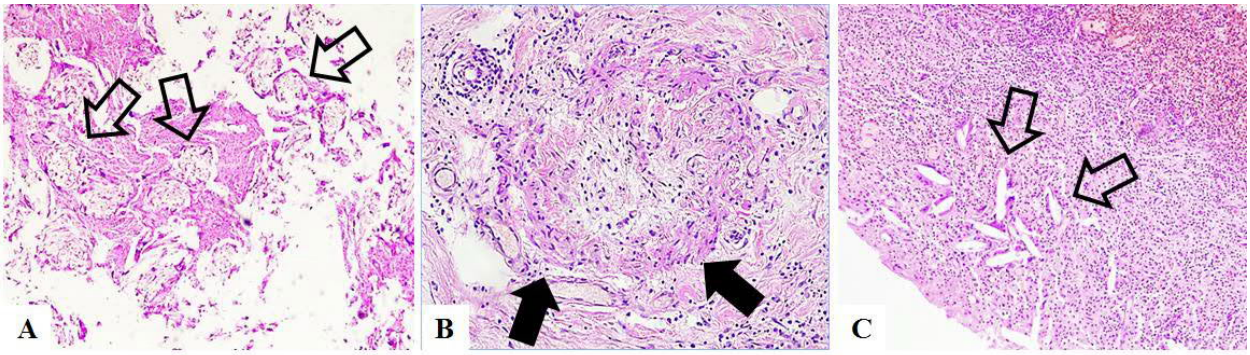

Figure 7. **Histopathological findings in abdominal textiloma**
(A) Case no.15: multiple macrophage-reactive granulomas with "thread" foreign body-type giant cells (arrows), HE, x200; (B) Case no.6: foreign body-type granuloma (arrows) with giant macrophage cells, HE, x400; (C) Case no.6: numerous chaotically arranged textile fibers (arrows), surrounded by inflammatory lymphocytic infiltrate, HE, x200.

Bacteriological examination was performed in 15 (65.21%) cases, mainly from purulent-like fluid from residual cavity after removal of acute textiloma. The inflammatory forms of textiloma were characterized by isolation of enteric group bacteria, while in chronic purulent external fistulas – nosocomial microorganisms. Generally, the bacteriological examination was of limited value in abdominal TFB, but it could serve as a criterion for the choice of antibacterial drugs for antibiotic prophylaxis and therapy.

4.4. Postoperative complications and consequences of abdominal textiloma removal

The problem of evaluating treatment results of abdominal textiloma is quite controversial. TFB retention in the abdominal cavity is "always wrong" and, from this position, all consequences of event, including infection, diagnostic tests to exclude possible neoplasm, the need for reoperation, fistula, bowel perforation or intestinal obstruction, are theoretically avoidable and therefore, unacceptable a-priori. Delayed diagnosis and treatment can lead to high morbidity and even mortality. Fortunately, there were no cases of death in our clinical series.

Summarizing the purely medical consequences and adverse events of TFB unintentionally left in the abdominal cavity, the following should be stated:

- Abdominal textiloma was symptomatic and caused clinical manifestations of varying severity in 21 (91.30%) patients;

- In only 4 (17.39%) cases, TFB was diagnosed in the early postoperative period, during the same hospitalization. All other 19 (82.60%) patients required a new admission;
- In 16 (69.56%) cases, TFB was detected up to six months after the causative laparotomy, and in 7 (30.43%) patients it remained undiagnosed for several years;
- Removal of TFBs from the abdomen required repeated surgery in 22 (95.65%) cases, of which 21 (91.30%) – through laparotomy and 19 (86.36%) – with general anesthesia;
- Repeated surgical intervention was performed in emergent settings in 12 (54.54%) cases, and major resection or reconstructive procedures was necessary in 4 (18.18%) patients;
- Severe postoperative complications were noted in 8 (34.78%) patients;
- The median length of in-hospital stays during which the abdominal TFB was removed was 13 (25%-75% IQR 8 – 26) days (range 4 – 73 days), while 5 (21.73%) patients had a length of hospitalization for more than a month.

In addition, there are other risks related to TFB retention and repeated operations for their removal. Assessing the cost of diagnostic tests, hospitalizations, treatment, surgery, and disability due to retention of abdominal TFB was not the purpose of this thesis, but it is undoubtedly very high. At the same time, not all costs can be measured financially. Iatrogenic complications, such as TFBs inadvertently left in the abdomen, are costly for patients and surgeons. Patients pay the price of physical and psychological discomfort due to unnecessary morbidity, prolonged hospital stay, the need to suffer painful procedures, and possible loss of health. For the surgeon, such events represent a serious personal problem due to the perception of intense psychological pressure from the patient and relatives, colleagues and administration of the medical institution, as well as feelings of guilt or even doubts about his own competence.

5. ETHICAL AND MEDICO-LEGAL ASPECTS OF TEXTILE FOREIGN BODIES LEFT IN THE ABDOMINAL CAVITY

5.1. Inconsistencies in medical records of abdominal textiloma

This chapter includes an unbiased analysis of 23 medical records from the clinical series, describing cases of abdominal TFBs detection and removal. Special attention was paid to the sections of medical document, in which the textiloma must be described as the cause of pathology, admission and redo surgery: preoperative conclusion, surgical report and description of gross specimen, postoperative and final diagnosis, epicrisis or hospital discharge papers.

Obtained data suggest that the “textile foreign body” was recorded in postoperative documentation in only 4 (17.39%) cases. In the remaining 19 (82.60%) patients, the postoperative diagnosis was composed as follows:

- “Abdominal or interintestinal abscess” – 6 (26.08%): cases no.5, 7, 9, 15, 18, 19;
- “Retroperitoneal or intraperitoneal cyst” – 3 (13.04%): cases no.3, 16, 21;
- “Purulent or organized hematoma” – 3 (13.04%): cases no.1, 4, 13;
- “Acute intestinal obstruction” – 2 (8.69%): cases no.12, 23.
- “Fibrolipoma” (case no.2); “cholelithiasis” (case no.10); “thread fistula" (case no.14); “bleeding gastric Dieulafoy lesion” (case no.17); “internal hernia” (case no.20) – one case each.

Surprisingly, out of 4 cases with truthful indication of abdominal TFB in surgical protocol and postoperative record, in two cases the real diagnosis later disappeared. Finally, only two (8.69%) of the 23 patients received official confirmation that TFB was left inside their body,

being the cause of their suffering. Thus, the true postoperative diagnosis was hidden and replaced by an alternative one in the vast majority of cases. Moreover, the operating surgeons sought to confirm the false diagnosis by more or less substantiated description of intraoperative findings in the surgical protocol.

Results of the study revealed deficiencies in medical documentation and its inconsistency with real data, including the intentional concealment of abdominal TFBs detection and removal, false description of imaging and intraoperative data, as well as replacing the true diagnosis with one fictitious alternative. Although the main role in correcting official documentation and concealing real information belongs to the operating surgeon, other medical collaborators, including radiologists, are also involved.

5.2. Assessment by surgeons of ethical issues associated with abdominal TFB

Numerous violations of medical ethics and dominant concealment of real information about the cases of identification and removal of TFB from abdomen, revealed in the histories of disease, determined additional study on surgeons' attitudes towards these problems. For this purpose, an anonymous survey was carried out among surgeons and obstetrician-gynecologists.

Asked if they could recall an incident during their career in which a TFB (sponge, tampon, towel) was accidentally left in the abdominal cavity, 193 (80.08%) surgeons responded positively. Generally, more than half (61%) of novice surgeons have a personal experience with forgotten TFB, and almost all (90-92%) of those with professional activity over 25 years.

One of the key questions was to provide the ethical and legal definition of accidental retention of TFB in the abdominal cavity. Almost half (46.88%) of respondents gave a "cautious" assessment of the event, characterizing it more as an accident, adverse effect or complication. Although by the most conservative estimates, TFB is undoubtedly a medical error. Moreover, most studies consider forgotten TFB to be a classic example of medical negligence or malpractice [5, 9]. It should be noted that the results of legal designation of events when CST was left behind in the abdominal cavity demonstrated poor awareness of surgeons and obstetrician-gynecologists of Moldova in medico-legal issues.

The following three questions were intended to clarify the current state of reflection in the medical records of TFB discovery and removal cases. The analysis of obtained results revealed that, although majority of respondents declare the need for truthful documentation of TFB cases (82%) and do not agree with the false description of intraoperative findings (67%), in reality the fact of detecting and extracting a TFB left in the abdomen was fully reflected in surgical protocol and in final diagnosis in only less than half (44%) of cases.

The results of a survey regarding personal responsibility of operating team members for cases of TFB left in the abdomen are shown in figure 8. Contrary widespread opinion about the main fault of operating surgeon (only 27.38% answered this way), respondents insisted on distributing responsibility to entire operating staff (39.0%), or dividing it between the surgeon and the operating nurse (24.48%), or even placing it entirely on the operating nurse (6.22%).

Thus, in full compliance with global trends, 70% of surgeons and gynecologists in Republic of Moldova, do not tend to assign all the blame for TFB left in abdominal cavity only to operating surgeon, emphasizing the need to share responsibility for event with the scrub nurse and the surgeon's assistant (or assistants).

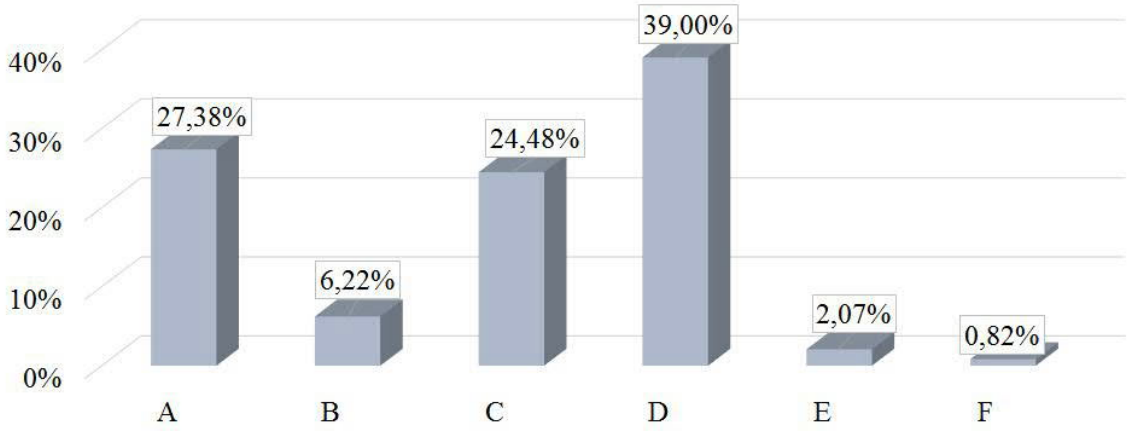

Figure 8. **Assignment of main responsibility of medical staff for forgotten abdominal TFB (n=241)**

(A) Operating surgeon; (B) Scrub nurse; (C) Both (operating surgeon and scrub nurse) equally; (D) Entire surgical team equally, including assistant surgeons; (E) Medical institution; (F) No one.

5.3. Probable medico-legal consequences of abdominal textiloma

The medico-legal consequences of TFB are often very significant. One hundred and seventy-two (71.36%) respondents believe that in the event of a legal claim for left abdominal TFB, the hospital should be responsible, along with the operative team. When asked about the hospital's involvement in such events, respondents most frequently indicated the improvement of patient safety, contribution in an informal agreement with patient and his relatives, participation of the hospital's lawyer in legal process, mandatory civil liability insurance for surgeons and payment of compensation in case of litigation loss (figure 9). Only 5% of respondents believed that no involvement of hospital is necessary in solving the problem at hand.

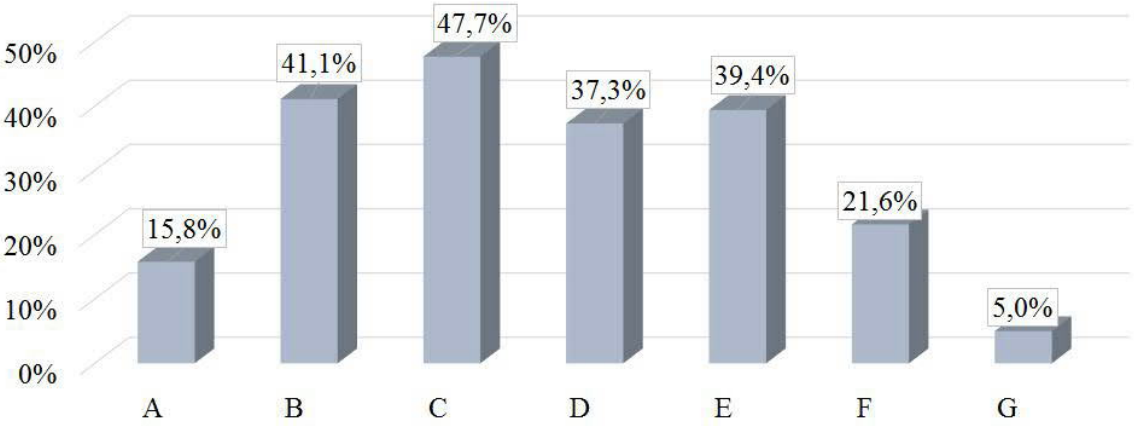

Figure 9. **Respondents' opinion regarding the appropriate form of medical institution involvement in case of a legal process for leaving TFB in the abdominal cavity**

(A) Punishing surgical team; (B) Contribution in an informal agreement between the parties; (C) Improving the institutional system of patient safety; (D) Introduction of mandatory liability insurance for surgeons; (E) Involvement of the hospital lawyer; (F) Payment of compensation in case of legal process loss; (G) Must not be involved.

Only 2.5% of respondents accept that it is appropriate to bring the guilty medical worker to civil or criminal liability. However, over 95% of respondents believe that professional discussion with possible disciplinary sanctions is the most appropriate response in the case of left intra-abdominal TFB. Many of such cases are not formalized and do not go to litigation, being limited

to internal disciplinary, corrective and educational measures. So, surgeons in the Republic of Moldova are aware of the existing shortcomings and hope for greater legal protection and institutional support from employers in the face of ever-present risk of human errors.

SYNTHESIS OF MEASURES TO PREVENT TFB RETENTION IN THE ABDOMEN

Universal standardization and adherence to safety protocols in the operating room should reduce the incidence of abdominal TFBs. Such a document was developed within this study – the National Guidelines "Surgical safety of patients in the operating room", approved by the Minister of Health of the Republic of Moldova no. 1226 of December 26, 2022 [15]. This document addresses ways to reduce the risk of various potential complications, including abdominal textiloma, to improve patient safety in the operating room and other settings where interventional surgical procedures are performed. In accordance with accepted practice, all medical institutions in the country are required to develop their own institutional surgical safety protocols based on the National Guidelines and, subsequently, to comply with their indications. Below are presented the provisions of the Guidelines regarding prevention of TFB retention in the abdomen.

Counting the textile objects (sponges, tampones, towels, swabs and others).

- Sponges should be packaged and delivered to the operating room in a standard quantity (eg 5 or 10) and then counted from this.
- Packages containing the wrong number of sponges should be removed from the sterile field and isolated, then repackaged and labeled.
- Swabs should be counted before starting the procedure, before closing any cavitary abdominal organ, before closing the wound (at the first layer), and when suturing the skin [8].
- During counting, the sponges must be completely separated from each other.
- The count should be performed by two persons, such as scrub nurse and operating surgeon. The objects must be viewed simultaneously by both staff members, and counted aloud.
- It is unacceptable to transfer swabs from one operating room to another. If there are not enough sponges in the operating room, a new package must be opened.
- It is also recommended to limit the number of sponges used during surgery, as well as to refuse the use of small swabs and tampons (not fixed on instruments).
- If possible, only sponges with radiopaque markers should be placed in body cavities for easy detection by radiological examination if count results are erroneous or counting is not possible.
- Any surgical intervention prior to definitive wound closure should be completed by a thorough methodical exploration of the wound / body cavity to rule out any remaining foreign bodies. Final examination of the wound by the operating surgeon is a mandatory measure even if the mesh count is considered correct.

Recording the count of surgical objects.

- Results of the count must be recorded in the operation protocol as "correct" or "incorrect".
- Gauze pads intentionally left inside the patient's body (eg, for hemostasis) should be documented in the medical record with their exact number, size, and location.

- Any action taken in case of inconsistency or counting error (recounting, searching for the lost object, x-ray and its results, notifying the board of the surgical service and the operating room) must be documented in the patient's medical record.
- Reasons for refusal from the surgical object counting procedure must be documented in the patient's medical record.

Mentioned recommendations emphasize the importance of systematic, professional, efficient, collaborative and complementary activities of all collaborators of the operating room, as being able to completely eliminate or minimize the risk of TFB retention inside the patients' body. Identification of accidental foreign body retention after surgery, in addition to strict reporting, should be subject to cause analysis, error investigation, and used for ongoing training of all operating room staff to avoid such events in the future and to improve patient safety.

GENERAL CONCLUSIONS

1. Although in most cases abdominal textiloma is symptomatic, its clinical manifestations are highly variable and often nonspecific, and can be interpreted as signs of common inflammatory postoperative complications (in the exudative form) or of tumor (in the fibrinous form), as a result of which the timely assumption regarding retained TFB is based on a high degree of clinical suspicion and should be considered as a possible diagnosis in any patient with an intra-abdominal mass of unknown origin and a history of laparotomy.
2. Significant risk factors for retention of abdominal TFBs include the urgent and prolonged surgery, major blood loss, the replacement of scrub nurse, as well as the disorganization of operating room work, manifested by lack of documentation and, possibly, the absence of sponges' real counting and thorough exploration of abdominal cavity before wound closure.
3. The most informative imaging method for abdominal TFB in both acute symptomatic and chronic asymptomatic forms is CT, which is able not only to accurately diagnose and localize the textiloma, its size and anatomical relationships with surrounding organs, but also to identify associated complications, such as fistulization of cavitary organs and intraluminal migration of the textile object.
4. The identification of textiloma serves demands open surgery as soon as possible to remove it from the abdominal cavity and prevent potential life-threatening complications. Although the most common volume of operation consists in simple extraction of textile object from the abdomen, the severe pathological changes of surrounding organs caused by abdominal TFB may determine the need of extensive resection procedures.
5. The adverse effects of unintentional retention of TFB in the abdomen include development of variable severity symptomathology, the need for re-admission and repeated laparotomy, often accompanied by extensive procedures, high postoperative morbidity and prolonged hospitalization.
6. There are significant contradictions between the declared adherent of surgeons and gynecologists to principles of contemporary medical ethics and their actual limited application in practice, regarding the truthful documentation and reporting of abdominal TBF cases, as well as the disclosure of information to patient and his family.

PRACTICAL RECOMMENDATIONS

1. Abdominal textiloma should be suspected in any patient with clinical manifestations of abscess, abdominal infection, intestinal obstruction, or abdominal mass of unknown origin who has undergone a previous laparotomy, based on careful evaluation of complines, objective signs, and history, as well as a high grade of clinical suspicion.

2. Any minimal suspicion of abdominal textiloma should serve as an indication for abdominal CT scan to confirm/exclude the condition safely, provide the accurate location and size of a mass, its anatomical relationships with adjacent organs and possible complications. The radiologist must have complete information about the purpose of examination and available clinical and anamnestic data, and have knowledge regarding visual characteristics of TFB.

3. When establishing indications for removal of abdominal textiloma, the possibility of developing urgent or unusual and threatening clinical situations caused by TFB must be taken into account, in which its definitive disclosure is largely an unexpected intra- or even postoperative finding.

4. Except special cases, for removal of abdominal TFB is justified open surgery, which is easier and faster, allows complete exploration of entire abdominal cavity, safer extraction of textile object, proper debridement and drainage of associated infected fluid collections, as well as correction of the most severe complications, such as erosion or fistula of hollow organs.

5. Hospital administrators should change a mode of action in the event of abdominal TFB disclosure from individual punishment of medical workers to objective investigation of circumstances, and search for ways to reduce the number of future incidents by implementing technical and organizational improvements, as well as increasing the level of institutional support and legal protection for surgeons.

6. It is necessary to raise the level of knowledge and awareness of surgeons and obstetrician-gynecologists in the issues of medical ethics and the potential medico-legal aspects associated with iatrogenic complications, which can be promote by legislative acts that provide a clear definition of medical error and malpractice, as well as the degree of individual and institutional responsibility of medical workers.

7. Each hospital must have appropriate rules and procedures for counting surgical items in the operating room, guaranteed known and learned by all staff. The document should specify when and who should perform the count, which objects should be counted and how to record the results of count (including inconsistent or erroneous ones).

8. Any surgical intervention prior to definitive wound closure must be completed by a thorough methodical exploration of the wound/body cavity to exclude retained foreign bodies. Final examination of the wound by operating surgeon is a mandatory measure even if the textile objects count is considered correct.

9. National health system authorities and hospital administrators should implement, as soon as possible, the globally approved measure to prevent TFBs retention – mandatory use during surgical procedures in deep cavities only of sponges with radiopaque markers for easy detection on radiological examination, as well as to analyze the possibilities of investments in other more sophisticated technologies.

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ABBREVIATIONS

TFB	textile foreign body
CT	computed tomography
AE	acute exudative [type to foreign body response]
CF	chronic fibrinous [type to foreign body response]
HE	hematoxylin and eosin [stain]
UH	Hounsfield units [of density]
USG	ultrasonography

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