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ABDOMINAL RADIOLOGY

Non-healing post-surgical fistulae: treatment with image-guided percutaneous injection of cyanoacrylic glue

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Abstract
Objectives To present the results of our experience with cyanoacrylic glue percutaneous injection to treat post-surgical non-healing enteric fistulae after failure of standard treatments.
Methods Eighteen patients (14 males; age range 33–84, mean 69 years) were treated for a non-healing post-surgical enteric fistula after failure of standard treatments. Under computed tomography and/or fluoroscopic guidance, a mixture of cyanoacrylic glue (Glubran 2, GEM, Viareggio, Italy) and ethiodized oil was injected at the site of the fistula. Fistula was considered healed when no material was drained by the percutaneous drainage and a subsequent computed tomography confirmed the disappearance of any fluid collection.
Results In all cases, it was possible to reach the site of the fistula using a percutaneous access. A median of 1 injection (range 1–5) was performed. Fistula healing was achieved in 16/18 (89 %) patients. One patient died for other reasons before fistula healing. Median time for fistula healing was 0 days (mean 8, range 0–58 days). No complications occurred. Reoperation was needed in one patient.
Conclusions Percutaneous injection of cyanoacrylic glue is feasible, safe, and effective to treat non-healing post-surgical enteric fistulae. It may represent a further option to avoid surgical reoperation in frail patients.

Keywords Cyanoacrilyc glue · Glubran · Enteric fistula · Percutaneous treatment · Image-guided technique

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Introduction

Gastrointestinal fistulae still remain a challenging clinical problem, with a wide range of manifestations, from the complete absence of symptoms to life-threatening septic shock [1] and may be burdened by a mortality rate up to 10 % [2]. Fistulae originate from an orifice of the intestinal tract or the biliopancreatic duct that drains digestive fluids or necrotic material to the skin or to other internal spaces [3, 4]. The etiology is iatrogenic in 75–85 % of cases, representing one common post-surgical complication. The incidence of anastomotic leakage ranges from 2.7 % for esophageal surgery to 25 % for pancreatic surgery [1, 5]. Fistulae have been reported to resolve spontaneously in approximately one-third of patients [3] with parenteral nutrition and medical therapy. Surgical reoperation in patients with non-healing fistulae can

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be challenging, being burdened by high rate of morbidity and mortality [1].

In the last decades, endoscopic and interventional techniques deeply changed the approach to post-surgical fistulae. Endoscopic treatments, with placement of clips, stents or different kind of sealants, have become more and more popular, as they allow to avoid surgery in selected high-risk patients [2, 6, 7]. On the other side, interventional radiology has played an increasingly important role in the management of a variety of post-surgical complications, offering a minimally invasive treatment for patients not suitable for endoscopy [8–16]. When all minimally invasive strategies fail, surgical reintervention is required, with increased morbidity and mortality rate and prolonged hospitalization [17].

To increase the success rate of percutaneous treatments, we recently described a novel technique of image-guided percutaneous injection of cyanoacrylic glue for the treatment of post-surgical enteric fistula [18].

The aim of this study is to present the results of our initial clinical experience using percutaneous image-guided cyanoacrylic glue injection in post-surgical non-healing enteric fistula after failure of standard treatments.

Materials and methods

Patient population

Approval was obtained by the Institutional Review Board and patient's informed consent was waived. We retrospectively reviewed data of 18 patients (14 males, 4 females; age range 33–84, mean 69 years) who were treated for an enteric post-surgical fistula in two different hospitals, between 2006 and 2014. In all cases, conservative or standard treatment (i.e., endoscopy, percutaneous drainage or percutaneous biliary drainage) failed in achieving fistula healing. Consequently, all the patients were treated with percutaneous local injection of cyanoacrylic glue (Glubran 2, GEM, Viareggio, Italy). Patients' characteristics are shown in Table 1.

Procedure details

Procedures were performed under computed tomography (CT) and/or fluoroscopic guidance by one of four interventional radiologists with 5–15 years' experience.

At these two institutions, when a post-surgical fistula is clinically suspected (e.g., for the presence of biliary fluid in the surgical drainage or the development of fever after abdominal surgery), the patient undergoes a contrast-enhanced CT. If a collection is detected, a percutaneous drainage can be placed. In case the collected material appears to be predominantly biliary, a percutaneous biliary drainage can be placed to divert the bile from the site of leakage. If the biliary leakage is still not controlled, a total external biliary drainage is attempted with the inflation of an occlusion balloon in the biliary tree [10, 11, 16]. If the fistula persists, the fistulous tract can be closed with a transcatheter injection of cyanoacrylic glue, composed of monomers of n-butyl-2-cyanoacrylate and methacryl-oxysulpholane. The glue is mixed with ethiodized oil (Lipiodol, Guerbet, Aulnay-sous-Bois, France) with a ratio of 1:2–1:5, to make the glue more fluid and to better visualize it on CT and fluoroscopic images. The correct amount of glue to use is still under debate and, nowadays, it is arbitrarily decided by the radiologist who performs the procedure. Before and after glue injection, the catheter has to be flushed with non-ionic dextrose solution, in order to avoid glue polymerization within the catheter itself.

Different percutaneous approaches can be used to inject the mixture (i.e., injection through a postsurgical drainage, through a previously placed percutaneous drainage, through transhepatic access in case of enterobiliary fistulae). Whatever the chosen approach, the operator tries to reach the site of the fistula and to place the catheter as close as possible to the fistulous tract before injecting the glue. Correct positioning of the catheter is confirmed by injection of contrast media. At the end of the procedure, a drainage catheter is left in place to maintain the access to the site and to check for fistula healing. The drainage catheter is then removed after few days, when a contrast-enhanced CT confirms the healing of the fistula and no material is drained by the catheter.

A case of treatment of a postoperative biliary fistula from the duodenal stump treated with percutaneous injection of cyanoacrylic glue is shown in Fig. 1.

In case of persistence of the fistula after the first glue injection, a subsequent fistulogram and a second injection of glue can be performed using the same route.

Data analysis

Feasibility of the procedure was defined as the possibility to reach the site of the fistula and to perform the glue injection as planned. Number of injections and time to achieve the complete closure of the fistula in each treated patient were recorded. Fistula was considered healed when no material was drained by the percutaneous drainage and a subsequent CT confirmed the disappearance of any fluid collection.

Results

In all cases, it was possible to reach the site of the fistula through a percutaneous access, using Flexima catheters

Table 1 Characteristics of 18 patients with enteric fistulae treated with percutaneous injection of cyanoacrylic glue

No.	Age	Sex	Basic disease	Surgical treatment	Site of fistula	N. glue injections	Healing time (days)
1	63	M	Gastric adenocarcinoma	Partial gastrectomy	Jejunum	3	25
2	82	M	Gastric adenocarcinoma	Partial gastrectomy	Duodenum	1	Immediate
3	76	F	Gastric adenocarcinoma	Partial gastrectomy	Duodenum	2	58
4	69	F	Colon adenocarcinoma	Right hemicolectomy with subsequent ileocolic resection	Colon	1	Immediate
5	59	M	Aortic dissection with bowel and cholecystic ischemia	Surgical aortic repair with bowel and cholecystic removal	Main bile duct	1	Immediate
6	78	F	Biliary tract adenocarcinoma	Duodenocephalopancreatectomy	Main bile duct	1	Immediate
7	79	M	Retroperitoneal tumor	Surgical resection with cholecystectomy	Duodenum	1	Immediate
8	84	F	Renal tumor	Partial nephrectomy and cholecystectomy	Right biliary duct	2	34
9	33	M	Pancreatic tumor	Duodenocephalopancreatectomy	Pancreatic tail stump	1	Immediate
10	78	M	Colon adenocarcinoma	Left hemicolectomy	Rectum	1	Nothealed
11	68	M	Gastric adenocarcinoma	Gastrectomy, splenectomy, pancreatectomy, left hepatectomy	Left biliaryduct	1	Immediate
12	68	M	Biliary tract adenocarcinoma	Surgical treatment	Pancreatic duct	1	Immediate
13	66	M	Biliary duct stenosis	Duodenocephalopancreatectomy	Jejunum-biliary	1	Immediate
14	77	M	Cholecystic adenocarcinoma	Cholecystectomy and partial hepatectomy	Biliary tract	1	Immediate
15	66	M	Duodenal ulcer	Partial duodenal resection	Duodenum	4	Partially healed[a]
16	81	M	Sigmoid diverticulitis	Sigmoid resection	Rectal fistula	1	Immediate
17	42	M	Sigmoid occlusion	Sigmoid resection	Rectal fistula	5	12
18	73	M	Rectal adenocarcinoma	Rectal anterior resection	Rectal fistula	1	Immediate

[a] Healing was achieved after 2 injections and lasted for 2 months, then the fistulous tract reopened. Two more glue injections were attempted, with no success. Thus, after 6 months, the patient was referred to surgery

(Boston Scientific, Natich, MA, USA) of different diameters (10–12 F).

A median of 1 injection (range 1–5) was performed to treat the patients, with most patients (12/18, 75 %) having received one injection. Full data are reported in Table 1.

In 11 cases (69 %) the fistula was immediately closed. Median time for fistula healing was 0 days (mean 8, range 0–58 days).

In all cases, no immediate or late procedure-related complications were seen.

In two cases, fistula healing was not achieved. One patient had a reduction of the output of the fistula without complete healing after one glue injection, but died during the hospital stay period due to acute renal failure and medullary ischemia before a second injection could be attempted.

Another patient was successfully treated with two glue injections but, after 2 months, the fistulous tract reopened. Other two injections of glue were performed in the following months but, after 6 months of medical and minimally invasive attempts, the patient was again referred to surgery, that was curative.

Discussion

Our work shows that percutaneous injection of cyanoacrylic glue is a feasible, safe, and effective strategy to treat non-healing post-surgical enteric fistulae.

The presence of a postsurgical fistula often requires an important effort of care, as it is associated with high morbidity and mortality rates. Moreover, it often implies an extension of hospital stay and cost increase due to the need of multidisciplinary management. Some systemic factors

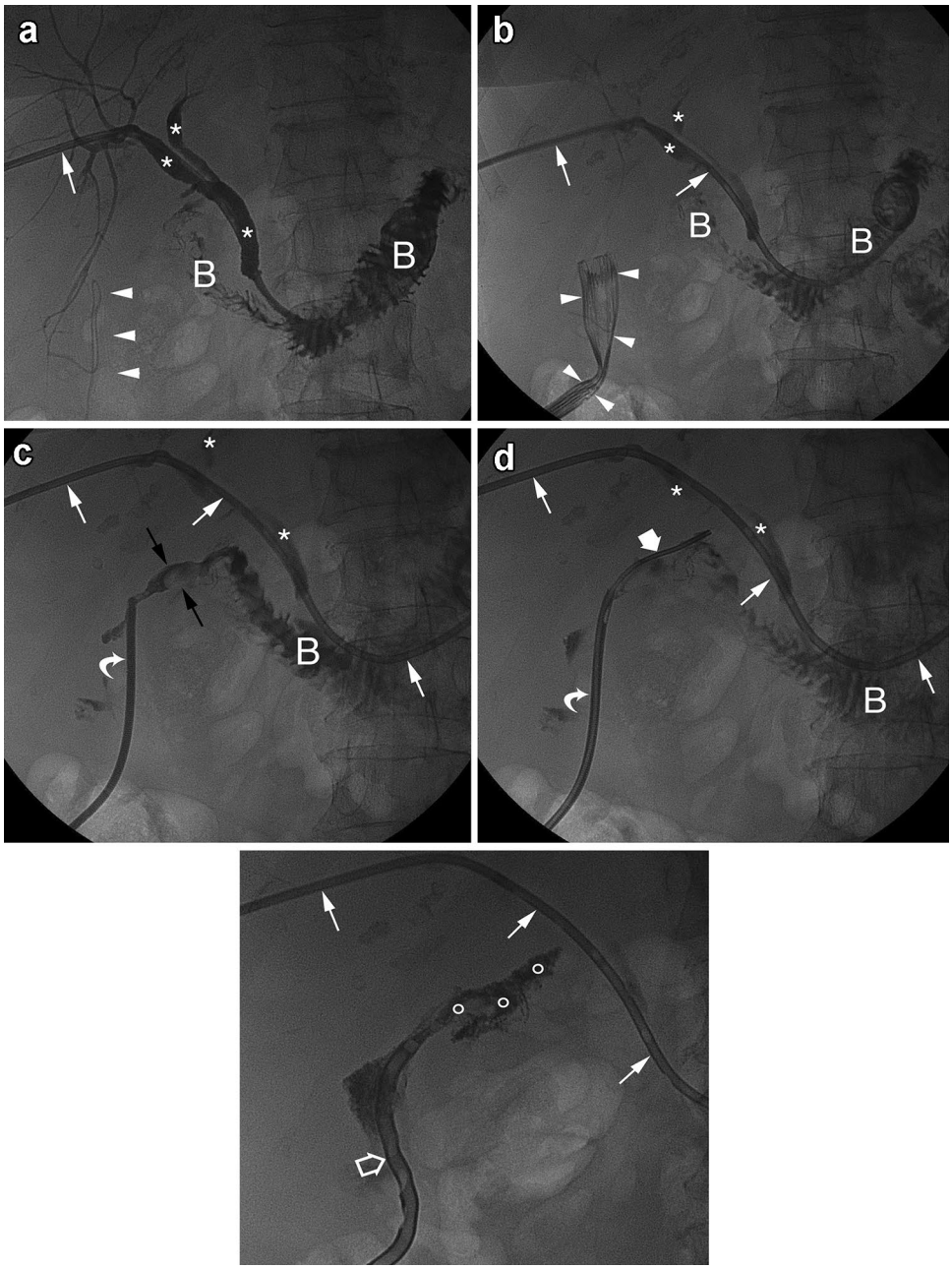

Fig. 1 Treatment of a patient with postoperative biliary fistula from the duodenal stump treated with percutaneous injection of cyanoacrylic glue. **a** A percutaneous transhepatic biliary drainage (*arrow*) is placed in order to divert the bile from the site of the fistula (*asterisks* biliary tree, *B* bowel, *arrowheads* postoperative surgical drainage). **b** Passage of contrast media from the percutaneous transhepatic biliary drainage (*arrows*) to the previously placed surgical drainage (*arrowheads*) is noted, demonstrating the passage of the contrast from the bowel to the drainage (*asterisks* biliary tree, *B* bowel). **c** A catheter (*curved arrow*) is placed into the surgical drainage and injection of contrast through it demonstrates opacification of the bowel (b) and the fistulous tract (*black arrows*) (*asterisk* biliary tree, *arrows* percutaneous transhepatic biliary drainage). **d** A microcatheter (*large arrow*) is inserted into the previous one (*curved arrow*) and advanced to the orifice in the bowel, and a mixture of Lipiodol and cyanoacrylic glue is injected at that level (*B* bowel, *white arrows* percutaneous transhepatic biliary drainage, *asterisks* biliary tree). **e** After the mixture is injected (*circles*) a drainage catheter (*empty arrow*) is left in place (*white arrows* percutaneous transhepatic biliary drainage)

increase the risk of a post-operative fistula, such as diabetes, tobacco and/or alcohol abuse [1]. In one-third of cases, conservative management, based on total parenteral nutrition and antibiotics administration, is sufficient to let the fistula close, generally within 6 weeks [3].

Furthermore, several surgical [3, 19] and mini-invasive [1, 20] innovations improved the management of fistulae in the past decades.

A number of endoscopic techniques have been proposed to treat post-surgical fistulae. Endoclips, mostly used to manage gastrointestinal bleeding, can also be used for closing gastrointestinal wall disruptions [21]. A retrospective evaluation performed at the Mayo Clinic Rochester and Virginia Mason Medical Center showed that clips (OTSC system; Ovesco Endoscopy AG, Tubingen, Germany) can close chronic fistulae with an initial success rate of 89 % with a six-month clinical success of 53 % [22]. Endoscopic stenting is another option: in case of benign disease, such as fistulae or leaks, fully covered stent are preferred to seal the defect and to avoid contamination. El Hajj et al. reported 15 patients with esophageal fistula treated with stent placement (Alimaxx-E; Alveolus Inc, Charlotte, NC or Ultraflex/Polyflex/Wallflex; Boston Scientific Corp, Natick MA), with primary closure achieved in 11 patients

(73 %) [23]. Endoscopic application of tissue sealants is another viable option to treat fistulae and leakages. The most common sealants used are fibrin glue and cyanoacrylate [24]. Fibrin glue can be applied after removal of tissue remnants around the orifice, as it gives better results when applied on a dry area [24]. Kotzampassi et al. reported the endoscopic application of fibrin glue [Beriplast P Combi Set (Aventis Behring, Marburg, Germany) or Tissucol Duo S (Baxter, Vienna, Austria)] and cyanoacrylate [*N*-butyl-2-cyanoacrylate (Histoacryl, B. Braun, Germany)] to close anastomotic leaks in 63 patients, reaching the goal in 61 of them [25]. High success rates were reported also in another series by Rábago et al. who reached the healing of the fistula in 87 % of cases after a mean time of 16 days and after a range of 1–5 fibrin glue (Tissucol) applications [26].

Several other techniques are available, such as suturing, grafts, biodegradable stents, cardiac septal occluders and endovac therapies that appear to be a valid option in selected cases but a clear clinical algorithm has to be developed to wisely choose the best option [24, 27].

In cases of unfeasibility of endoscopical treatment, percutaneous approach may be a viable option. For what concern the role of interventional radiology, several procedures have been reported to reduce the reoperation rate in patients with postsurgical complications.

Abscesses and underlying fistulae have been widely treated with percutaneous drainages under CT or US guidance [10–12] with good results, as reported by Kelogrigoris et al. [13], who treated 21 patients affected by post-surgical infected collections, or by Laganà et al. [14] who treated 107 patients. They reported progressive shrinkage of the collections in the midterm in 85 and 91 % of patients, respectively.

In case of fistula with predominantly biliary content, percutaneous transhepatic biliary drainages have been successfully used to divert the bile from the site of the fistula, with a good rate of fistula healing and a reported reduction of recovery time [8, 9, 13, 14]. The positioning of an occlusion balloon above the site of the fistula together with total external biliary drainage may further increase the rate of biliary fistula healing [10, 11].

However, all these percutaneous techniques are aimed to enhance the spontaneous closure of the fistula. Thus, finding a way to actively close the fistulous tract might be helpful in shortening the recovery time.

In our series of patients not recovering after standard interventional treatments, surgery would have been the only possible solution, with increased risks. Thus, an attempt of achieving the closure of the fistula with the percutaneous application of glue was considered in a multidisciplinary discussion as a viable option.

In the past years, some techniques have been described in order to directly close fistulae and some case series are reported in literature. However, evidence is still sparse, in particular regarding enteric fistulae and the best material to be used as sealant [28–33].

Fibrin glue, already used in surgical [32] and endoscopic [34] settings, has been introduced in interventional radiology to manage fistulous tracts and small series reported good results [33]. Gelatin sponge (i.e., Gelfoam by Pfizer Inc., New York, NY, USA) is a low-cost material that is widely used to stop hemorrage. Its use in the management of chronic enterocutaneous fistulae has been reported by Lisle et al. [35] who treated 3 patients with good results.

Cyanoacrylate mixed with Lipiodol has been already tested by Cambj Sapunar et al. in 6 patients with low-output enterocutaneous, being successful in 100 % of cases [36].

Bae et al. described 11 patients with enteric or biliary fistulae, unresponsive to drainage and then treated with cyanoacrylic glue injection (Histoacryl, B. Braun, Germany). In all patients, enteric or biliary fistula output ceased after one or two procedures without any complications [28]. In our study, we used a different cyanoacrylate-based material. Compared to others, Glubran 2 has a different chemical composition that has been reported to produce a more elastic and stable polymer, also resulting in lower inflammatory reaction [37, 38]. Glubran 2 provides some advantages over other embolic materials, as it offers a fast adhesive strength able to firmly close the fistulous tract. This is due to the fact that its components (monomers of *n*-butyl-2-cyanoacrylate and methacryl-oxysulpholane) start to polymerize when they come in contact with living tissues, generating a film with high tensile resistance in about 60–90 s. and it has an antibacterial property that facilitates the application on infected sites [24].

Moreover, Glubran 2 can be easily visualized under fluoroscopy once mixed with Lipiodol. The amount of Lipiodol to be added to the glue can be established case by case, in accordance to the desired fluidity of the mixture. In our experience, a variable ratio of 1:2–1:5 has been used with good results in terms of sealing and visibility, and without complications during follow-up.

Some limitations of the present study have to be taken into account. First, this is a retrospective analysis of a limited number of patients with limited clinical information and generally short follow-up. However, all these patients had a fistula involving the gastrointestinal tract that was not sealing with standard care and would have required surgical repair. Then, the amount of Glubran 2 to be injected and the rate of dilution with Lipiodol were not standardized, and were chosen case by case by the interventional radiologist performing the procedure. Thus, final conclusion on the exact amount of glue to be injected cannot be derived by the present paper. Moreover, the attempt of sealing the fistula by glue injection was always made after failure of

standard treatments after different times from the onset of the fistula. Further studies are needed to better clarify the issue, and in particular to understand the exact amount and dilution of the glue, the better time for application of the technique, and to understand which kind of patients could be benefit more from this kind of procedure.

Conclusion

Percutaneous injection of cyanoacrylic glue seems to be a feasible, safe and effective strategy to treat patients with non-healing postsurgical fistulae. This approach represents a valuable novel minimally invasive technique and a potential alternative to surgical reoperation in those patients with post-surgical fistulae that are non-healing after standard minimally invasive management.

Compliance with ethical standards

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

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was waived by the relevant Institutional Review Board.

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