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Review Article

Chemical characterization, adverse effects and potential toxicological effects of medical devices applied in gastrointestinal disease: a review

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ABSTRACT

Medical devices have gained popularity as a therapeutic or diagnostic purpose in gastrointestinal obstructions caused by malignant tumour or benign stricture or any other pre-existing conditions. The problems of stents are like sense of foreign body, migration or incomplete expansion or re obstruction. In this scenarios, self-expandable metallic stents (SEMS), or biodegradable self-expanding stents, wall flex stents, drug eluted stents, etc prevents the obstruction related difficulties. SEMS associated with re-obstruction and migration along with difficulty in removal and chances of leaks due to corrosion. In case of biodegradable self-expanding stents, which are either made of magnesium-based materials or synthetic polymers, such as polylactide or polyglycolide, or co-polymers, such as polydioxanone. Magnesium-based materials are very biocompatible but due to the property of dissolving in the body by rapid corrosion, degradation can occur before the therapeutic objective is reached. Synthetic polymers associated severe mucosal hyperplastic reaction with overgrowth and/or ingrowth. Wall flex stents, drug eluted stents can be used to prevent complications associated with above variants but their clinical significance and toxicological effects were not evaluated completely. Under this given scenario toxicological evolution of various medical devices used in gastrointestinal disease and their potential toxicological effects are required to understand their tolerability and acceptability.

Keywords: Medical devices, SEMS, Gastrointestinal diseases, Toxicological effects

INTRODUCTION

The gastrointestinal (GI) obstruction is major cause of morbidity and mortality in patients with various benign and malignant tumours of the gastro intestinal tract (GIT). Few decades earlier, the surgical procedures (open/laparoscopic) were been used mostly for the primary management of these conditions and its complications. The shortcomings of surgical procedures were invasiveness, high cost, longer hospital stay and surgery related complications. With the advent of metallic stents in the management of obstructive symptoms of GIT has overcome the above shortcomings.[1]

Initial indication of metallic stents was for the management of malignant dysphagia caused by oesophageal lesion. Later on, different these stents were successfully used for the management of various lesions in the oesophagus, stomach, duodenum, biliary tract, pancreas and colon.[2]

Earlier, hard plastic stent was indicated for palliation of GI obstruction due to benign and malignant conditions. However, plastic stent was not well accepted due to procedural difficulty, along with primary and secondary complication rate along with poor compliance. In 1990s, plastic stents were replaced by the SEMS with simple

insertion technique and less complications and well tolerated.[3]

Though SEMS are more frequently used, stent migration, tumour overgrowth or ingrowth causes recurrent obstruction. To reduce the above complications newly designed SEMS, or biodegradable self-expanding stents, wall flex stents, drug eluted stents etc. indicated.[4] SEPS indicated in oesophageal obstructions whereas SEMS indicated in both oesophageal and gastroduodenal obstructions.[5,6]

Material used in metal stents, alloys such as stainless steel, nitinol and Elgiloy. Later alloys have greater degree of flexibility and maintains its position at the site of insertion by generating high radial forces. Nitinol is the most commonly used as a material for SEMS and it contains various proportions of nickel and titanium, which is responsible for flexibility and shape after therapeutic application.[7] Newer SEMS prepared either covered or partially covered with a coating of silicone or plastic membrane.[5] Covered SEMS stents are effective in the preventing obstruction, but due to loss of the positional memory as well as flexibility more prone for the migration.[8]

SEPS are prepared in various concentrations of silicone and polyester. SEPS used in oesophageal obstructions due to tumour growth. Minimal tissue reaction, local inflammation and good patient tolerability makes SEPS comparable with metallic stent. However, SEMS associated with displacement from site of insertion and SEPS associated procedural difficulty during insertion.[6,9,10]

Now a days another type of stent used which is made up of biodegradable polymeric materials. These stents disintegrate and dissolve from the site of insertion or migrated site and excreted from the body without residual effect.[11]

CHEMICAL CHARACTERIZATION OF MATERIAL AND ITS ADVANTAGES

Materials for GIT stents, primarily derived from metals and their alloys, like stainless steel, Elgiloy-Phynox, and nitinol or non-degradable polymers (polyester), or biodegradable polymers such as polyglycolide, polylactide, and polydioxanone.[12]

SEMS

SEMS made of stainless steel, cobalt-chrome alloy, and nickel-titanium alloy. Chemical characterization of each material described below.

Stainless steel: the only stainless steel which is made of austenitic 316L stainless steel is used for manufacturing the implants. The 316 L stainless steel constitutes nickel chromium-molybdenum steel with low-carbon, with constituents at different proportions (Fe 63 wt%, Ni 10-14 wt%, Cr 16-18 wt%, Mo 2-3 wt%).[13,14]

Cobalt-chrome alloy or Elgiloy-Phynox: This is an austenitic cobalt-based alloy with a composition of various metals at given proportions Co 40 wt%, Cr 20 wt%, Ni 16 wt%, Mo 7 wt%. It is free from magnetic activity, highly resistance to corrosion, as it is not sensitive to corrosion by organic acids or inorganic acids. The bio-compatibility with human tissue shows an excellent passivity.[15]

Nickel-titanium alloy or nitinol: Duerig et al observed that, nitinol is made of equal proportions in terms of atomic weight of nickel and titanium with different proportions of weight (Ni 55 wt%, Ti 45 wt%).[16] Stoeckel et al described various reasons for nitinol's effectiveness as a medical device. These are thermal deployment, constant stress, kink resistance, dynamic interference, stress hysteresis elastic deployment, and temperature dependence of stress. Nitinol also exhibits magnetic resonance imaging (MRI) compatibility, corrosion resistance, and biocompatibility.[17]

Self-expanding plastic stent (SEPS)

The currently available SEPS is the Polyflex stent, made of a plastic wire and it is fully covered with silicone and a proximal flare. This stent material effective in preventing reactive tissue hyperplasia. Holm et al observed that 80% of individuals relived their signs and symptoms of dysphagia in benign oesophageal strictures.[18]

Biodegradable (BD) polymer materials

The BD stent has been developed to minimise the shortcoming with SEPS. The shortcoming with SEPS are high migration rate, poor long-term efficacy, and multiple interventions. Biomaterials of BD polymers are combination of magnesium-based alloys with synthetic polymers. The chemical constituents in synthetic polymers are poly-glycolic acid (PGA), poly-lactic acid (PLA), poly-dioxanone (PDX), poly-caprolactone (PCL), and poly-lactide-co-glycolide. Magnesium based alloys are shown to have good biocompatibility and completely dissolved inside the human body during the degradation process. However, this property may lead to premature degradation and corrosion resulting in the less efficacious.[19]

The presently available BD stent are the ELLA-BD stent (polydioxanone), and the poly-L-lactic acid (PLLA)-BD stent. Polydioxanone is a semicrystalline, biodegradable polymer and it is highly sensitive to low pH. The PLLA consists of knitted monofilaments and relatively resistant in low pH.[20,21]

Drug-eluting stents

The first models (first phase models) were applied in 1999. They had a more complex structure as they gradually

released a drug. They consist of a metal part and a polymeric cover which contained a drug (Myolimus, novolismus and other antiproliferative drug). However, the polymeric coating is one of the causes of the pathogenesis of long-term stent failure by inducing a potential chronic inflammation.[22] In some stents they are coated with anti-tumour drugs like 5-fluorouracil or paclitaxel to prevent tumour ingrowth.[23]

Covering materials for enteral stents

Covering materials used along with stainless steel, and self-expanding plastic stent materials. The most commonly used materials for covering enteral stents are silicone, permalume silicone, or polyurethane. Durability of polyurethane is very low around 2-4 weeks due to its predisposition to early degradation. Silicone is the most promising material for GIT stent covering because of its resistance to degradation, mechanical properties, and biocompatibility. The covering also prevents the ingrowth of tumour in case of malignant disease and facilitates its retrieval.[24]

CLINICAL APPLICATION AND RELATED COMPLICATIONS

Oesophageal obstruction

In the treatment of benign or malignant oesophageal diseases, SEPS or SEMS indicated. Currently about 12 SEMS and SEPS marketed across the world. Among this only two are available as uncovered.[25] SEPS are cost effective, their insertion is easy, and tissue reaction at the site of insertion is less compared to SEMS.[26] However, polymeric stents are highly prone for migration to other sites of GIT.

Taking the above concerns oesophageal obstruction due to the malignant tumour managed with the SEMS. Because, SEMS made of mesh structure that enables for self-expansion after its insertion in the oesophagus and, it restores passage of the oesophagus. However, tissue in-growth across the mesh stature causes obliteration of passage as well as life-threatening bleeding. During this condition, the surgical removal may be warranted.[27]

These shortcomings can overcome with the use of biodegradable polymeric stents. The BD polymeric stents like Ella oesophageal stent need not be extracted from the site of migration in GIT. Considering its benefits, BD polymers are highly effective in the treatment of benign oesophageal strictures.[28]

Gastroduodenal obstruction

Obstruction at the gastroduodenal obstruction outlet is the common complication of later stages of duodenal malignancy, or distal gastric malignancy, or periampullary malignancy. Different types of metal stent are indicated in this condition.[29]

Woo et al demonstrated that, the use of uncovered SEMS/SEPS preferred over covered SEMS/SEPS in malignant duodenal obstruction because of longer patency and lower rate of stent migration.[30] However tumour ingrowth and obstruction is the most common complication with uncovered stents.[31] Newer stents like, double- and triple-layer stents made of covered and uncovered stents. In this variant covering part of the stent is sandwiched between two nitinol self-expanding SEMS. These newer variants theoretically superior in minimising the complications associated with covered or non-covered SEMS/SEPS in obstruction at gastroduodenal junction.[3] The rate of biliary obstruction after gastroduodenal stent also observed and its frequency range between 1.3% to 11%.[3]

Biliary obstruction

Clinical application of stents in this condition traced from 1979. Initially a straight, or slightly curved variants were used. Currently pigtailed polymeric stents are commonly used.[32,33] Polymeric stents are available at variable lengths (5 to 18 cm) and diameters (7 to 12 Fr), with or without side holes, and anchoring flaps at the end to reduce potential migration after their insertion. SEMS are relatively larger in diameter, along with self-expanding, and covers the biliary epithelial cells after implantation. The major disadvantages of SEMS compared to SEPS are high cost, and difficulty in repositioning after insertion, therefore not indicated in benign strictures.[34] The duration of patency is high and the rate of obstruction is less compared with the SEPS. However, due to tumour ingrowth and fatal bleeding are the major concerns with SEMS. In an attempt to reduce the incidence of tumour in growth in the SEMS, covered stents with the silicone indicated.[35-37]

Large bowel obstruction

Obstructive symptoms in colonic malignancy seen in 8-29% of patients. Obstructive symptoms present in advanced stages of colonic cancer and these patients will have about 27% more chances of liver metastasis than non-obstructive patients.[38] SEMS is gaining popularity among coloproctologists. It has shown to be effective in relieving symptoms of obstruction in patients who are either unfit for major resection or have advanced malignancy.[39] There are two indications for colorectal stent insertion in cases of malignant obstruction, these are palliative care for un-resettable metastatic patients to relive the signs of obstruction and acute obstruction before surgery. Insertion of SEMS is a safe strategy and effective in intentional obstruction. Dohmoto et al published his work on successful stent placement in malignant colorectal cancer with obstruction.[40] Different stents suitable for colorectal stenosis described in Table 1 from Keymling et al.[41] Frequent complication are tumour invasion, or obstruction due to fecolith or foreign body.[40]

Table 1: Characteristic properties of stents used in colon.

Stent	Diameter (mm)	Length (cm)	Covered	Delivery system diameter (Fr)	Placement in rectum/colon	Manufacturer
Wall stent enteral	18-22	60, 90	-	9	+/+	Boston scientific
Ultraflex	25		+	18	+/+	Boston scientific
Endocoil	18/24	100/150		32	+/-	InStent
NiTi-S	20/22/24	60/90/100	+	24		Teawong Medical
Z-stent	18/25	10/12/14	+	24	+/-	WilsonCook

ADVERSE EFFECT OF GIT STENTS AND TOXICOLOGICAL EFFECT

Stent migration

Stents migration can be due to misplacement or displacement after insertion over a period of time. Migration of stents commonly seen with covered SEMS/SEPS because poor adherence with adjoin tissue.[42] Stent migration may be asymptomatic or may cause haemorrhage, obstruction, and perforation.[43,44] Perforation after stent migration relatively less common, however in anatomic abnormalities like strictures, diverticula/hernias, precipitates perforation induced by a migrated stent.[45]

Fracture of a stent

Primarily associated with bleeding from site of insertion or recurrent obstruction. The causes fracture includes, spontaneous, cancer ingrowth or re growth, procedural failure with argon plasma coagulation.[46]

Stent obstruction

Stent obstruction can result from tumour regrowth or ingrowth reactive tissue hyperplasia, luminal impaction with sludge or stones, or food, or feces, etc.[47,48]

Stent collapse

Stent collapse is a less common phenomenon and relatively late complication, occurring in patients with longer survival times. Primary cause is due to compression of tumour from outside.[44,49]

Superinfection

Superinfection associated with cholangitis and liver abscess. It is a late squeal of implants. Commonly seen with SEPS stents in biliary obstruction.[47,50]

Haemorrhage

Either during procedure or late haemorrhage. Overall, the incidence of haemorrhage is less common than above adverse effects of stents. However, severe haemorrhage can occur in about 6% of patients. Primary cause for haemorrhage is due to erosion of oesophageal vessels by the stent or to local tumour invasion in uncovered SEMS.[46] Hyperplasic tissue reaction: Hyperplastic tissue reaction occurs in SEMS due to local erosion and corrosive reaction. In some instances, severe tissue hyperplasia may result in relapse of disease.[19] Summary of complications described in Table 2.[46]

Table 2: Primary and secondary complications of stents depending on its site of insertion.

Site of stent insertion	Primary complications	Secondary complications
Esophageal stenting	Stent migration, and death	Stent obstruction, chest pain, recurrent dysphagia, gastroesophageal reflux, hemorrhage, fistulisation, perforation
Colorectal stenting	Stent migration, procedural failure, and death	Stent obstruction, tenesmus, and perforation
Biliary tract stenting	Stent fracture, stent migration	Stent obstruction, biliary obstruction, cholecystitis, cholangitis, pancreatitis, liver abscess, perforation, hemorrhage.
Gastric and duodenal stenting	Stent migration, procedural failure, and death	Stent obstruction, perforation, hemorrhage

TOXICOLOGICAL EFFECTS RELATED TO INDIVIDUAL MATERIALS

Stainless steel 316 L

most common toxicological effect of this material will be crevice corrosion as compared to the other implant

alloys.[13,14] Briefly, corrosion is a process of degradation of metals due to electrochemical reactions at the site of its insertion. Metallic implants are highly prone for such reaction. Corrosion can result in reduced lifespan of stent along with local complications like reactive tissue inflammation, irritation or burning sensation, bleeding etc.[51]

Self-expanding nitinol oesophageal stent

Toxicological effects of self-expanding nitinol oesophageal stent include massive destruction of wire mesh in central portion and stent fracture due to massive corrosion. Such complications can be minimised using covering material.[52]

SEPS

The SEPS used for biliary obstruction associated with clogging. Chemical analysis of the constituents of the clogging material from biliary endoprostheses shows the presence of ethylene-vinylacetate copolymer instead of polyethylene as declared by manufacturers. Costa et al concluded that SEPS not the primary choice in biliary obstruction as it causes the phenomenon of clogging with the polyethylene even though polyethylene has higher flexibility.[53] The clogging tendency of SEPS associated with recurrent jaundice and pruritus. Motte et al observed that, patients with signs of cholangitis (jaundice and pruritus), are highly prone for life threatening sepsis. Considering the SEPS in biliary obstruction replaces with SEMS.[54] Lorenzo-Zúñiga et al observed that biodegradable stents associated with premature losing of radial force, stent-induced mucosal or parenchymal injury, etc. resulting in displacement.[19]

Biodegradable stents

The biodegradable stents primarily made of magnesium alloys. Magnesium alloys have very high corrosive rates in the biological fluid, due difference in pH and ion distribution. Such materials can be modified by adding pH buffering agents like anion-/cation- exchange resins.[51]

CONCLUSION

GIT obstruction due to benign or malignant lesions effectively relieved by inserting stents. Stents used in GIT are SEMS, SEPS, biodegradable stents and drug elution stents. SEMS and SEPS provides durable effects, but due to corrosion and clogging respectively causes stent failure along with local tissue reaction, inflammation, hyper proliferation of tissue, and bleeding. Biodegradable stents require multiple insertions due to migration and dissolution. Drug eluting stents prevents the hyperplastic local tissue reaction, but corrosion and stent failure remain major limiting factors. Overall, apart from local adverse and toxicological effects of stents and there is need for long-term systemic effects need to understood to provide sustainable clinical benefits.

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