The British Society of Interventional Radiology

British Society of Interventional Radiology

ROST - Registry of Oesophageal Stenting

First Report 2004

Compiled by

Hans-Ulrich Laasch MRCP FRCR
Stephen Lee FRCS FRCR
Jon G Moss FRCS FRCR
Carl Roobottom MRCP FRCR

British Society of Interventional Radiology

Robin Kinsman BSc PhD
Peter K H Walton MA MB BChir MBA

Dendrite Clinical Systems Ltd

The British Society of Interventional Radiology

ROST
Registry of Oesophageal Stenting
First Report
2004

Compiled by

Hans-Ulrich Laasch MRCP FRCR

Stephen Lee FRCS FRCR

Jon G Moss FRCS FRCR

Carl Roobottom MRCP FRCR

Robin Kinsman BSc PhD

Peter K H Walton MA MB BChir MBA

British Society of Interventional Radiology

Dendrite Clinical Systems Ltd

The British Society of Interventional Radiology
gratefully acknowledges the assistance of
Dendrite Clinical Systems Ltd
for
data analysis
and publishing this report.

Dendrite Clinical Systems Ltd is registered
under the Data Protection Act
Data Protection Act Register Number
Y33 54 136

October 2004 Edition. A catalogue record for this book is available from the British Library. ISBN 1-903968-11-9

Published by:

Dendrite Clinical Systems Ltd, 59A Bell Street, Henley-on-Thames, Oxfordshire RG9 2BA, United Kingdom

Contact details: Phone: (+44) 01491 411 288, Fax: (+44) 01491 411 377, E-mail: publishing@e-dendrite.com

Printed and Bound by CPL Associates

Foreword

THE ROYAL COLLEGE OF RADIOLOGISTS

TEL: 020 7636 4432
FAX: 020 7323 3100

38 PORTLAND PLACE
LONDON W1N 4JQ

Ref : 290704/PD/British Soc Interventional Radiology

29th July 2004

The British Society of Interventional Radiology
4 Verne Hill
Ampthill
Bedford. MK45 2PS

Re : Oesophageal Stent Registry

The Royal College of Radiologists is committed to the development of robust standards against which performance can be measured. The College publishes standards on the responsibilities of individual Clinical Radiologists, departments, on equipment specifications, procedures and outcomes. The British Society of Interventional Radiology has an enviable record in undertaking structured review of the provision of services, publication of standards and audit. Some of this work has been in collaboration with the Royal College of Radiologists such as the development of standards in Vascular Radiology and the current audit of percutaneous nephrostomy, while in other studies the BSIR has produced work under the aegis of, for example, NCEPOD.

However, the commitment of BSIR to the development and maintenance of high standards within interventional radiological procedures is manifest by a growing body of work undertaken by its members, which addresses outcomes for procedures across a large number of contributing centres. The BIAS study published in 2001, for example, became the yard stick for procedures and outcomes in iliac angioplasty. This current work, the oesophageal stent registry, evaluates the performance of a variety of oesophageal stents, predominantly for malignant disease. Complications relating to the nature of sedation, the nature of the procedure and the design of the stent are addressed.

The collection of data from seventeen different NHS Trusts allows the practitioner to measure his or her outcomes against results achieved in a wide variety of institutions. It also provides information which will allow the most appropriate choice of stent for individual case management.

The work of the BSIR and those of its members who have contributed to the oesophageal stent registry are to be congratulated on its development. On behalf of the Royal College of Radiologists I would wish to thank all of those who contributed.

Dr Paul Dubbins
Vice President and Dean
Faculty of Clinical Radiology

Registered Charity No. 211540 VAT Registration No. 706 9665 05
E-mail: enquiries@rcr.ac.uk Internet: http://www.rcr.ac.uk

Preface

For some time now it has been the policy of BSIR to generate registries that record the day-to-day practice of British Interventional Radiologists. This document is the product of the oesophageal stent registry, which closed (temporarily) to recruitment at the end of 2003. It is clearly of value for interventional radiologists to have such a registry to give a snapshot of practice, which details not only the indications for a procedure but also the outcome in terms of success and complications. This is obviously a useful tool for Clinical Governance in that whilst published studies usually report experience from expert single centres, this registry gives a much better indication of current practice.

There are some disadvantages in that not all interventional radiologists undertaking oesophageal stenting have contributed to the registry and, indeed, only radiologists have submitted patients. Many oesophageal stents in Britain are placed by endoscopists and it would be interesting to compare the findings from this registry with the National Confidential Enquiry into Patient Outcome and Death on therapeutic endoscopy. It will be the aim of BSIR to reopen this registry with some changes made in the light of experience and make it open to all gastroenterologists, surgeons and radiologists who place oesophageal stents. In this way I hope that we will be able to get a better view of this diverse practice.

Naturally I think it is to the great credit of the BSIR that this and other registries are able to contribute to a better understanding of interventional techniques. My personal thanks go to all of those who have contributed to the creation and management of the database and particularly to those who have produced this report.

Derrick F Martin

President of the British Society of Interventional Radiology

Contributors

City / Town	Hospital / Centre	Name	Department
Bristol	Southmead Hospital	Dr Mark J Thornton	Radiology
Camberley	Frimley Park Hospital	Dr Andrew Hatrick Dr Alison Keightley	Radiology
Chorley	Chorley & District Hospital	Dr Robert Stockwell	Radiology
East Kilbride	Hairmyres Hospital	Dr Sam Millar	Radiology
Eastbourne	Eastbourne District General Hospital	Dr Hugh J Anderson Dr David V Hughes	Radiology
Falkirk	Falkirk Royal Infirmary	Dr Emma J Beveridge	Radiology
Glasgow	Gartnavel General Hospital	Dr Jean Pierre Charon Dr Jonathan Moss Dr Ian Robertson Dr Richard Edwards Dr Des Alcorn Dr G Annamalia Dr P Scott	Radiology
Llantrisant	Royal Glamorgan Hospital	Dr Eryl Hicks	Radiology
Manchester	South Manchester University Hospital	Dr Ruth England Dr Hans-Ulrich Laasch Prof. Derrick Martin	Radiology
Margate	Queen Elizabeth the Queen Mother Hospital	Dr Giorgio Giancola	Radiology
Nottingham	Nottingham City Hospital	Dr Craig Jobling Dr Adrian Manhire	Radiology
Oxford	John Radcliffe Hospital	Dr P Boardman Dr Jane Phillips-Hughes Dr Raman Uberoi	Radiology
South Shields	South Tyneside District Hospital	Dr Lance Cope	Radiology
St Leonards-on-Sea	Conquest Hospital	Dr Keith Foord Dr John Giles	Radiology
Sutton in Ashfield	King's Mill Centre for Health Care Services	Dr Philip Panto	Radiology
Taunton	Musgrove Park Hospital	Dr Hywel Thomas Dr Richard Keogan	Radiology
West Bromwich	Sandwell General Hospital	Dr Francis Leahy	Radiology

Table of contents

Executive summary

This reports demonstrates that:

- Data collection for a national database is possible
- Efforts need to be made to include more centres in the future
- Oesophageal stent insertion by radiologists is safe and effective
- Sedation administered for this procedure has a low complication rate
- The use of anaesthetic and hypnotic drugs is variable and should be unified in the light of the recent guidelines
- A large variety of stents are being used on the basis of operator preference rather than scientific evidence
- Some operators may not be aware of changes in licencing of stent use
- Removable stents and anti-reflux stents are being under-used
- Modern stents have a low complication rate, but migration remains a problem
- Re-intervention is frequently required, either involving endoscopy or further stent placement. The incidence increases with time after stenting; continued patient follow up is essential.
- Further research is needed regarding:
    - Timing of stenting
    - The use of temporary stenting
    - The impact on the patients' nutritional status

Introduction

In January 2002 the British Society of Interventional Radiology (BSIR) launched the Registry of Oesophageal Stenting (ROST) to look at the practice of oesophageal stenting within the UK. The decision to study a non-vascular procedure underpinned the role the BSIR plays in embracing all types of interventional radiology.

415 patient records were collected by 29 radiologists from 17 centres over a two-year period to December 2003. It was an adventurous project riding on the success of the BSIR iliac angioplasty and stent registry (BIAS) in 2001. Patients were followed up at 1, 3 and 6 months, a task not to be underestimated. It is a tribute to the BSIR and its membership that the registry collected such good data on so many patients.

The quality of a report can only be as good as the quality of data collected and herein lie some of the issues that now need to be addressed in the future. Not all radiologists and centres participated and therefore the application of the results to the population at large may be compromised. It is likely that the size of data-set, the long term clinical follow up and lack of financial support for the project deterred some radiologists. It is uncertain how many centres did not participate and the compliance rate can only be guessed. We do know that 71 radiologists initially registered for ROST but only 29 supplied any data. Did the participating centres enter all potential patients? No; in one centre (Glasgow) for example 59 patients were stented over the study period but only 20 entered into ROST. More focus and support is required to allow these types of registry to function properly. Ideally a data manager is required to ensure compliance and accuracy, though it is suspected that there are currently few available in the average UK radiology department. It took several years and the Bristol inquiry for compliance to reach 100% in the cardiothoracic registry (2004 cardiothoracic registry).

Oesophageal stenting is not of course the sole prerogative of an interventional radiologist who shares this procedure with gastroenterologists and surgeons. It is hoped that future registries of this type should be multidisciplinary and would allow an interesting comparison between different operators and specialties.

It was not possible on this occasion to use risk modelling methodology (to compare individual operators) due to the relatively small numbers involved. Funnel plots were used instead to allow comparison between centres and radiologists. As with BIAS individual radiologists have not been identified in the ROST report alongside the results. The Society of Cardiothoracic Surgeons of Great Britain and Ireland has for the first time in its latest 2004 report [1] published results for individually named surgeons. Like it or not this is the system in which we now work, we either lead it or have it done for us.

The BSIR was founded upon the principles of developing the science of Interventional Radiology and, until the BIAS report, had made no attempts to engage in national data-collection. The ROST registry is the second to be reported and demonstrates our ability to continue this kind of work in spite of an ever-increasing general and administrative workload.

Other BSIR registries are currently recruiting (fibroid embolisation, thoracic stent grafts & carotid stents) and others are about to be launched (nephrostomy & radiofrequency ablation). We should welcome these initiatives openly and devote the appropriate time and resources. The surgeons have been doing it for years, NICE have told us to do it for fibroid embolisation – we are rapidly responding, watch this space.

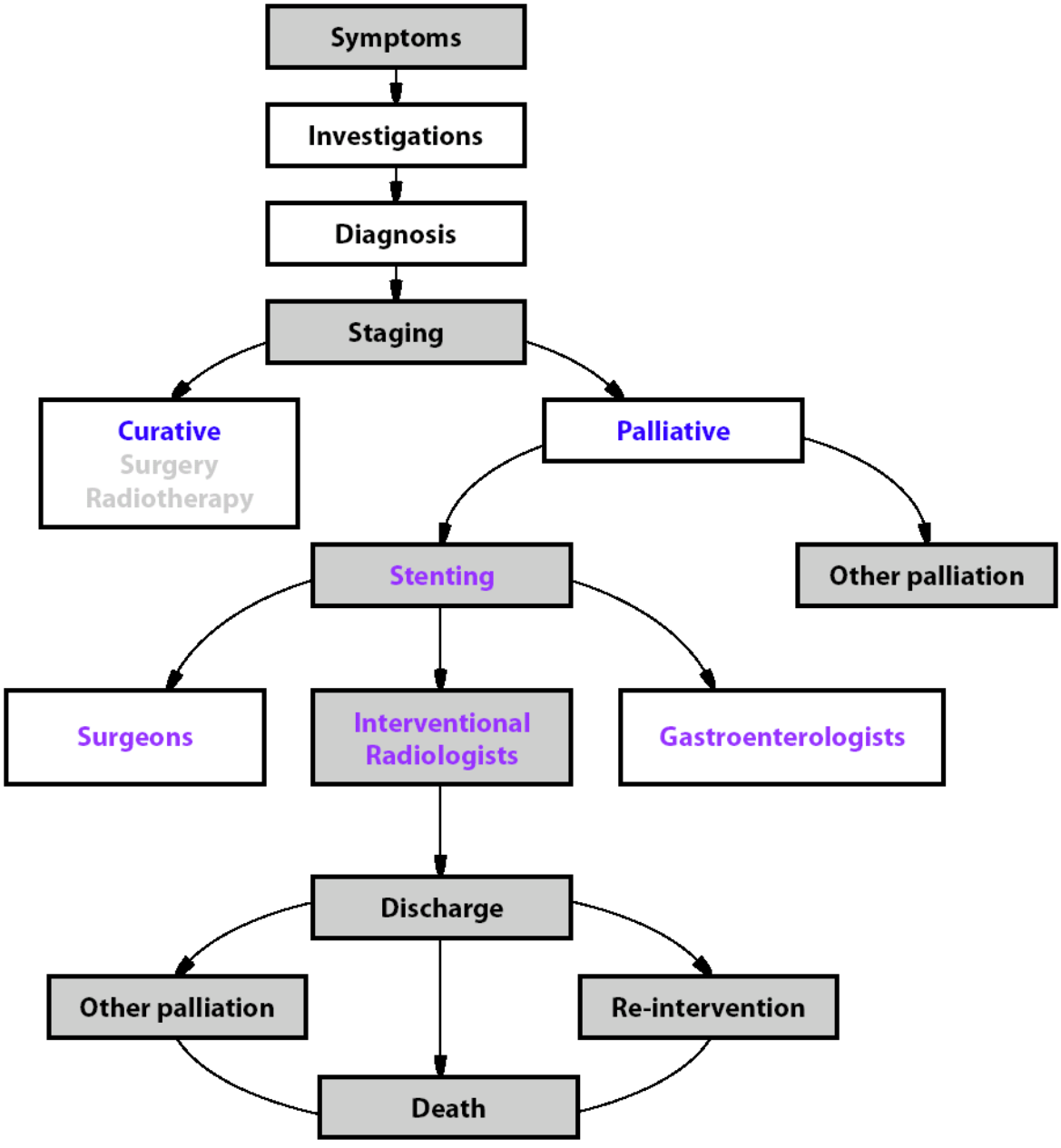
We would like to thank all those BSIR members involved in developing the project, all participating BSIR members for contributing to the work, Lavinia Gittins for the data entry task and Peter Walton and Robin Kinsman of Dendrite Clinical Systems for running the data analysis programs and publishing the report.

Jon Moss
Audit Committee Chair, BSIR

Carl Roobottom
Past Chairman, BSIR Audit & Registries Subcommittee.

Patient-journey diagram

The boxes with grey backgrounds denote the points at which data are captured for the ROST registry.



Stenting procedure

The radiological insertion of oesophageal stents has been described in detail [2]. After topical throat anaesthesia the patient is placed in a comfortable position allowing easy monitoring and access to the mouth and airway. A prone or prone/oblique position reduces the risk of aspiration, with a left-posterior-oblique position giving the best projection of the cardia. All patients must be pre-oxygenated and adequately monitored. Sedation is performed by slow titration of short acting benzodiazepines (*e.g.* Midazolam), which may be supplemented with opiates (*e.g.* Fentanyl). The procedure itself causes little discomfort, but stent expansion can cause chest pain. If opiates are used, these should be given before the hypnotics, to minimise the risk of respiratory depression [3]. Wherever possible anaesthetic support should be sought, but it is often not available. The patient should be monitored by a dedicated nurse, who assesses the patient regularly. Clinical assessment during the procedure is difficult [4] and can be improved by using EEG monitoring [5].

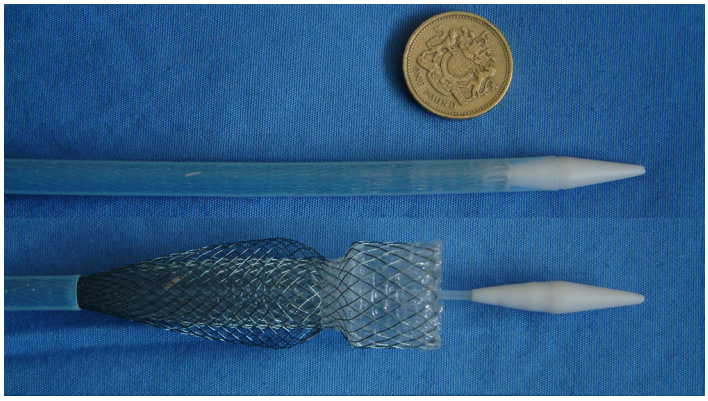
Through a mouthguard the oesophagus is intubated, using a torquable angled catheter and a hydrophilic guidewire. Once the stricture has been negotiated the wire is removed and non-ionic contrast injected while withdrawing the catheter. The extent of the stricture is marked with metal markers taped to the patient's skin. Note must be taken of the anatomy of the gastric fundus in order to prevent embedding of the distal end of the stent.

After re-insertion of the hydrophilic wire the catheter is placed into the stomach and the wire exchanged for a stiff wire of at least 180 cm length. The stent delivery system is lubricated with jelly and inserted under screening. Balloon dilatation of strictures carries a high risk of complications [6], but is virtually never required with slim pull-back delivery systems, where the stent is constrained by an outer sheath.

If exact stent positioning is difficult, the introducer system may be advanced a little further than required, the distal end is released and the whole system carefully pulled back into final position for complete deployment. Initial expansion is often limited, but will improve over several days. Follow-up swallow investigations are only required in symptomatic patients [7]. Detailed dietary advice reduces the risk of food bolus impaction and helps patients regain confidence to eat.

Patients' awareness of the stent increases with positioning close to the cricopharyngeus muscle. Stents requiring placement in the cervical oesophagus should be removable in case of intolerance. Where the distal end of the stent has to be placed in the stomach, debilitating reflux is common, which can lead to fatal aspiration [8]. This is significantly reduced by the use of stents with an anti-reflux valve [9,10,11,12].

A large variety of oesophageal stents are now available but not much comparative data exists. Virtually all oesophageal stents are covered by a membrane to prevent tumour in-growth into the stent. The stent skeleton may consist of individual segments connected by string or the covering membrane, a mesh of intertwined wire strands or it may be woven from a single length of wire. The materials used are stainless steel, a nickel-titanium alloy with shape memory (nitinol) or in one instance polyester (Polyflex stent). With one exception the delivery system consists of an outer sheath which constrains the stent and deployment is by pulling back the sheath (see picture below). The Ultraflex stent is compressed onto the delivery system by a thread, which gradually releases the stent on traction. The main differences between stents are their flexibility, the presence of an anti-reflux valve and whether they are removable. Stents with a high radial force tend to expand quicker, but do not conform as well to anatomical curves (*e.g.* gastro-oesophageal junction) or peristalsis.



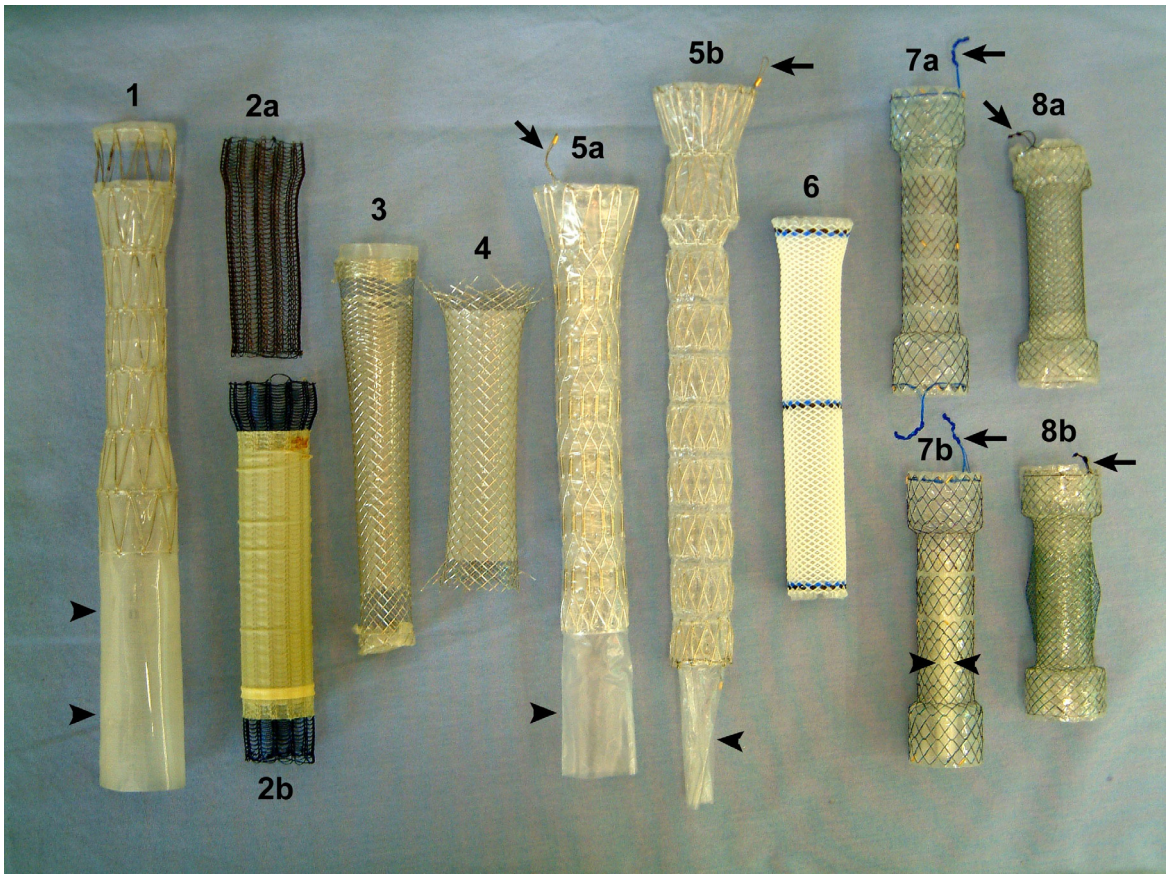
Distal end of a 20 Fr. pull-back delivery system & part-deployed stent (Niti-S double stent).

Stents are frequently chosen on the basis of operator preference and ease of use [13], rather than matching different stent properties to the patients and their needs.

Current stent models

The following table summarises the properties of oesophageal stents currently available in the UK. The Fer-X Ella and the Do stent were significantly modified during the period of data collection, whereas the Niti-S series only became available at the end of 2003. The indications for the use of the Flamingo Wallstent were revised in 2001. Since then, the device is only licenced for placement in the lower oesophagus [14]. Information is as supplied by manufacturers.

Current stent models



1	Gianturco stent with Dua anti-reflux valve
2a	Uncovered Ultraflex stent
2b	Covered Ultraflex stent
3	Flamingo Wallstent
4	Wallstent Oesophageal II (Covered Wallstent)
5a	Removable Fer-X Ella anti-reflux stent (Initial version)
5b	Revised Fer-X Ella anti-reflux stent (Boubella)
6	Polyflex removable plastic stent
7a	Removable Choo stent
7b	Removable Do anti-reflux stent with internal valve (revised version)
8a	Removable Niti-S single stent
8b	Niti-S double stent with outer uncovered segment

Arrows denote retrieval string for removal / repositioning and arrowheads denote anti-reflux valves.

Current stent models

Manufacturer	Cook		Boston-Scientific		
Stent	Gianturco	Dua	Ultraflex	Flamingo	Wallstent oesophageal II [i]
Launched / modified	1994	2000	1994/1997/ 2004	1998	2000
Material	Steel	Steel	Nitinol	Steel	Steel
Construction	Segments	Segments	Weave	Cut wires	Cut wires
Cover PU=Polyurathane PE=Polyethylene	PU	PU	PU	PU	Silicone
Valve	-	Windsock	-	-	-
Removable	No	No	No	No	No
Available length / cm	8-14	8-14	10-15	10-15	10-15
Delivery system / Fr [ii]	31	31	22	15.5 / 18	18
Pre-assembled	No	No	Yes	Yes	Yes
Deployment	Sheath	Sheath	String	Sheath	Sheath

Manufacturer	Ella-CS	M.I. Tech [iii]		Ruesch [iv]	Tae Woong [v]	
Stent	Fer-X Ella	Choo	Do	Polyflex	Niti-S single	Niti-S double
Launched / modified	2002/2003	1999	2000/2002	1999	2003	2003
Material	Steel	Nitinol	Nitinol	Polyester	Nitinol	Nitinol
Construction	Segments	Segments	Segments	Mesh	Weave	Weave
Cover PU=Polyurathane PE=Polyethylene	PE	PU	PU	Silicone	PU	PU
Valve	Windsock	-	Windsock	-	-	-
Removable	Yes	Yes	Yes	Yes	Yes	No
Available length / cm	12-19.5	8-17	9-16	9-15	6-15	6-15
Delivery system / Fr	20	18	25	36-42	20	20
Pre-assembled	Yes	Yes	Yes	No	Yes	Yes
Deployment	Sheath	Sheath	Sheath	Sheath	Sheath	Sheath

[i] Referred to as *Covered Wallstent*

[ii] French size: circumference in mm; Diameter [mm] = French size divided by π

[iii] Distributed by Diagmed

[iv] Distributed by Pilling Weck

[v] Distributed by Pyramed

Demographic data

Age

The median age of all patients was 74 years (range 30–93 years); the median age for male patients was 72 years (range 30–93 years) and for female patients 79 years (range 36–93 years). This difference was statistically significant (p<0.001).

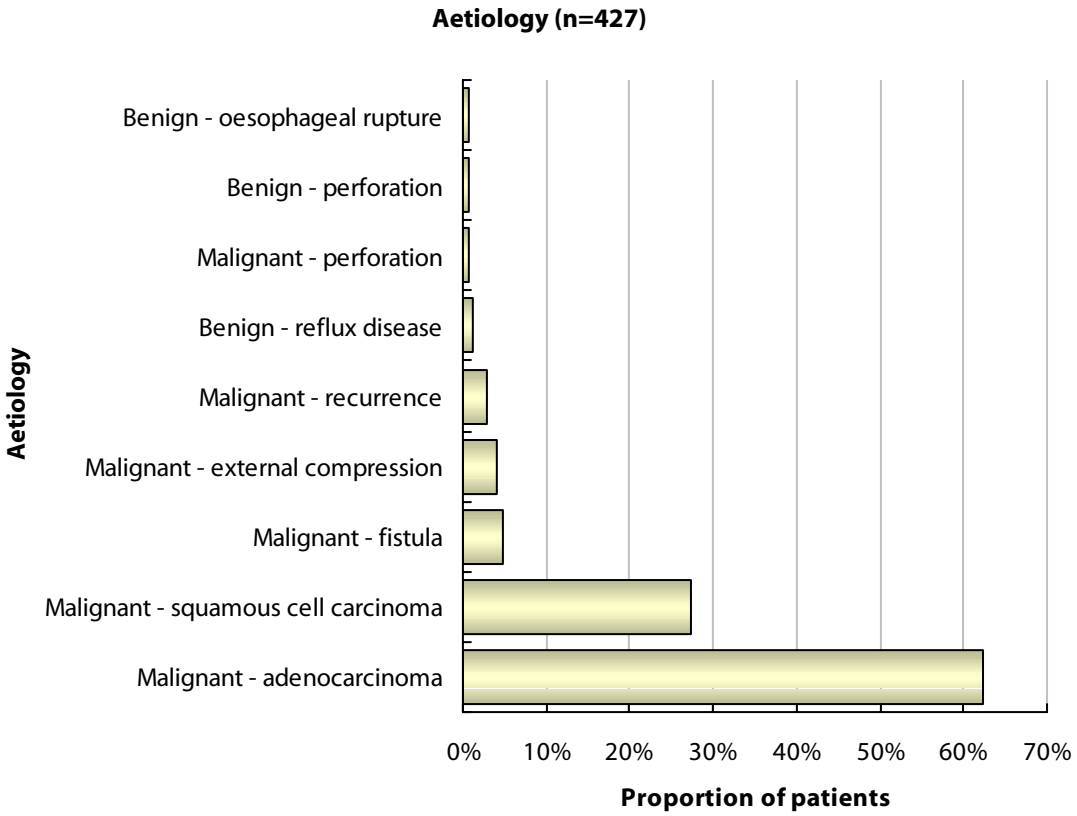
		Gender			
		Male	Female	Unspecified	**All**
Age at stent placement / years	<51	18	1	0	**19**
	51-60	43	16	1	**60**
	61-70	70	23	2	**95**
	71-80	96	53	2	**151**
	>80	57	69	4	**130**
	Unspecified	2	0	1	**3**
	All	**286**	**162**	**10**	**458**

Pathology

Aetiology

Almost two thirds of patients had an adenocarcinoma arising in the lower oesophagus. This is in line with the rapidly increasing incidence of this tumour. It is likely that gastro-oesophageal reflux disease and Barrett's metaplasia are important factors, but this has yet to be shown conclusively.

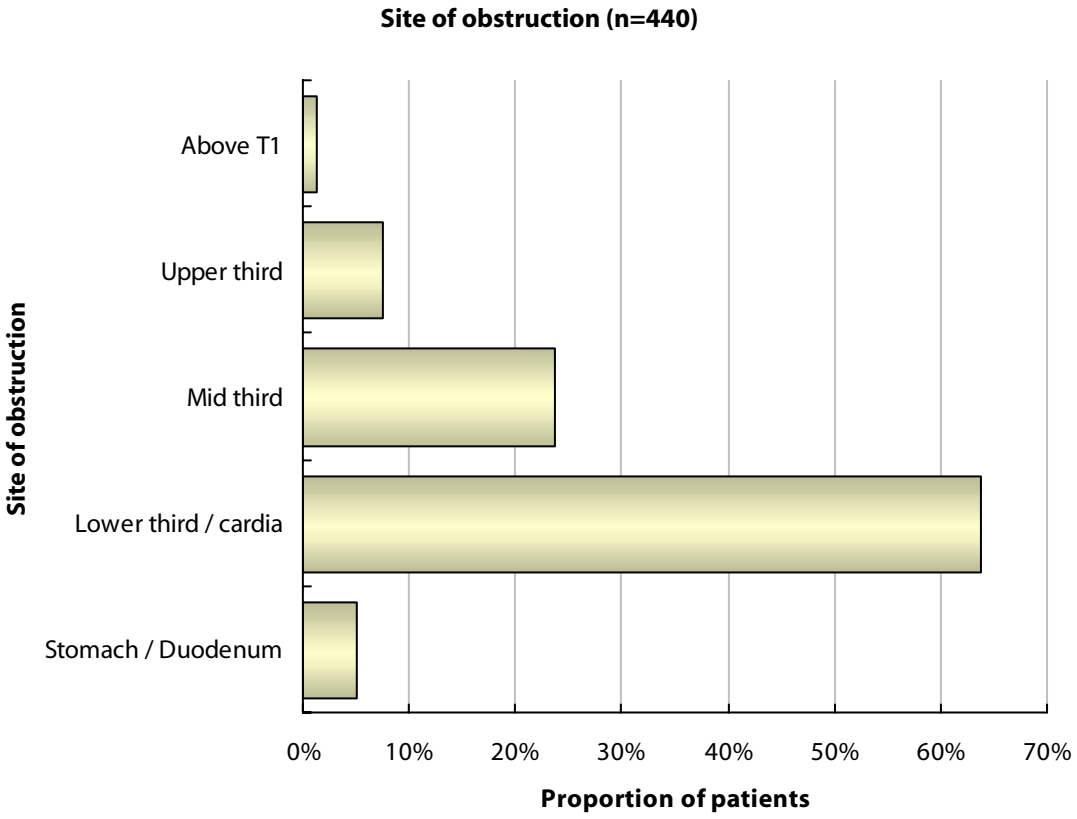
Stenting for benign oesophageal disease has a limited role and is only used as a last resort with 2.5% being placed for this indication.



Site of obstruction

The use of oesophageal stents above the T1 level was limited to a small group of 6 patients, which is due to the low incidence of tumours at this site as well as the perceived patient intolerance to stents placed in the cervical oesophagus.

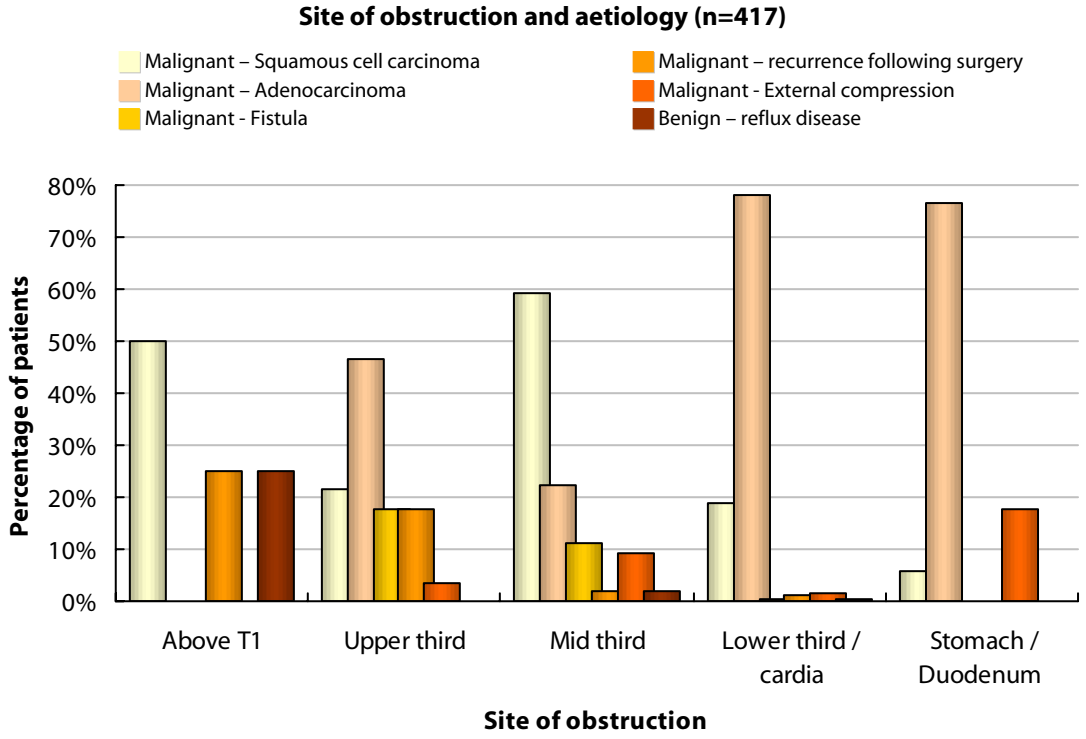
Some oesophageal stents were placed below the cardia despite the fact that dedicated enteral stents are available for this site.



Site of obstruction and aetiology

The observation of a significant proportion of patients with upper third tumours being adenocarcinoma is unexpected and may include some lung cancer patients with oesophageal invasion.

		Site of obstruction						
		Above T1	Upper third	Mid third	Lower third	Stomach / Duodenum	Unspecified	**Patient denominator**
Aetiology	Malignant - Squamous cell carcinoma	2	6	58	51	1	1	**117**
	Malignant - Adenocarcinoma	0	13	22	211	13	10	**266**
	Malignant - Fistula	0	5	11	1	0	3	**20**
	Malignant - Recurrence post-surgery	1	5	2	3	0	1	**12**
	Malignant - External compression	0	1	9	4	3	0	**17**
	Malignant - Perforation	0	1	0	2	0	0	**3**
	Benign - Perforation	0	1	1	0	0	1	**3**
	Benign - Oesophageal rupture	0	0	1	1	0	1	**3**
	Benign - Reflux disease	1	0	2	1	0	1	**5**
	Unspecified	2	5	6	11	5	3	**31**
	Patient denominator	**6**	**33**	**104**	**281**	**22**	**18**	**458**



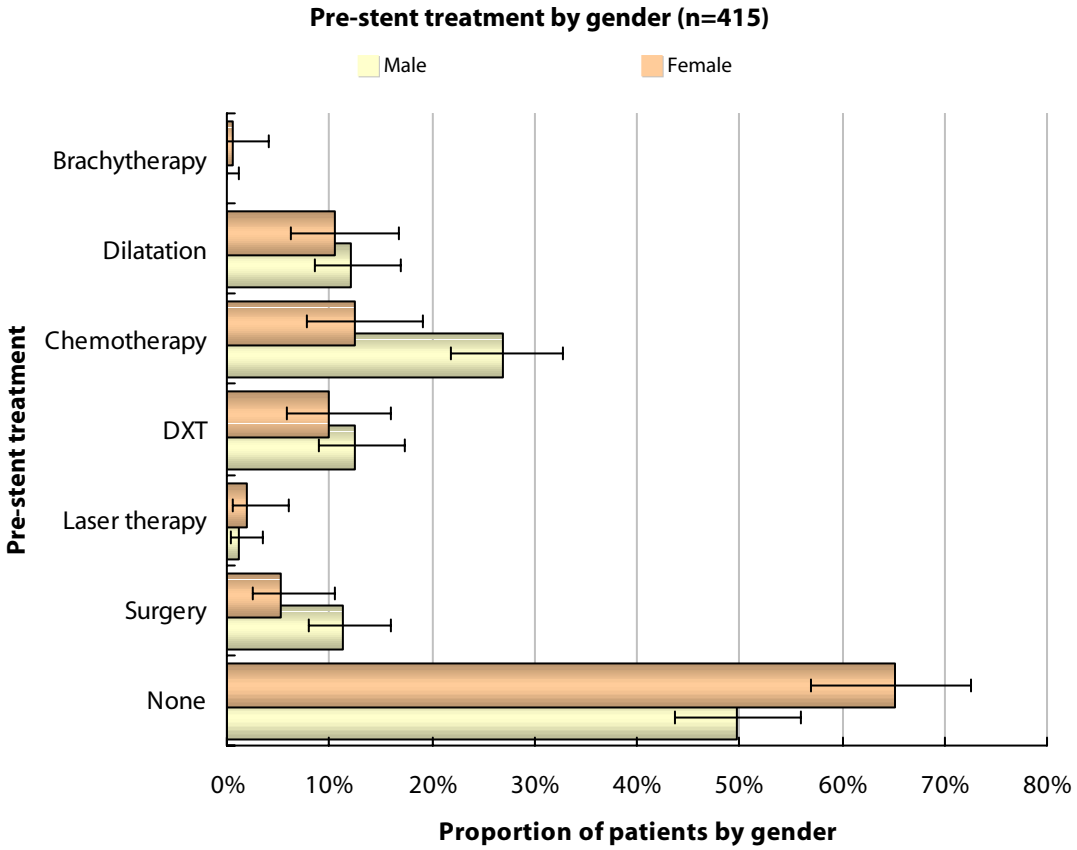
Procedure

Pre-stent treatment

Pre-stent treatment by gender

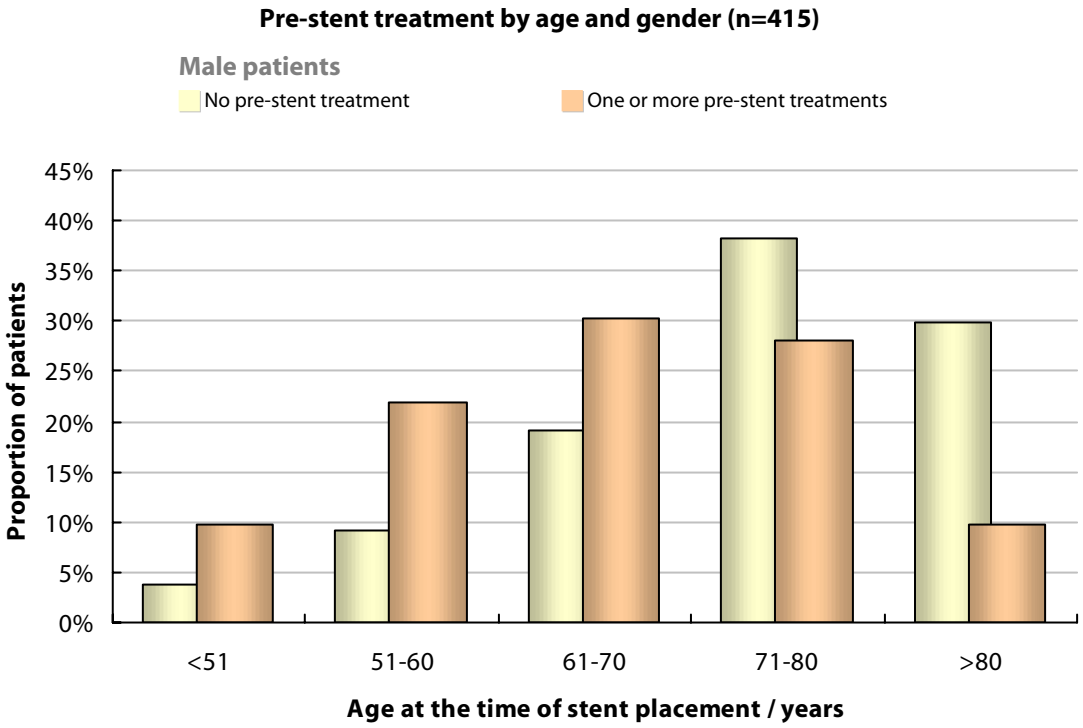
Just under 45% of all patients received some form of palliation prior to stent insertion, indicating that these procedures are complementary.

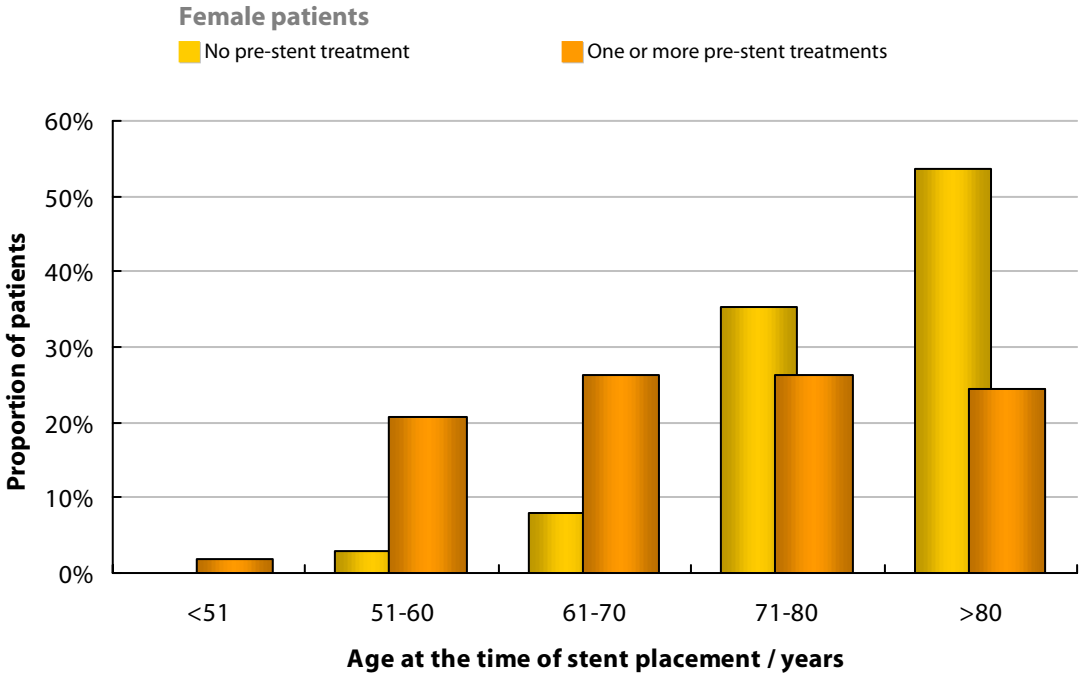
Men were more likely to have had previous therapy than women (50% *versus* 35%; $p<0.05$). It is unclear whether this relates to a difference in the general condition, the stage of the disease at presentation, patient's age at presentation or a selection bias towards men.



Pre-stent treatment and age

Younger patients were more likely to have had other treatment prior to stenting. For patients over 70 years it was the palliative measure of first choice.





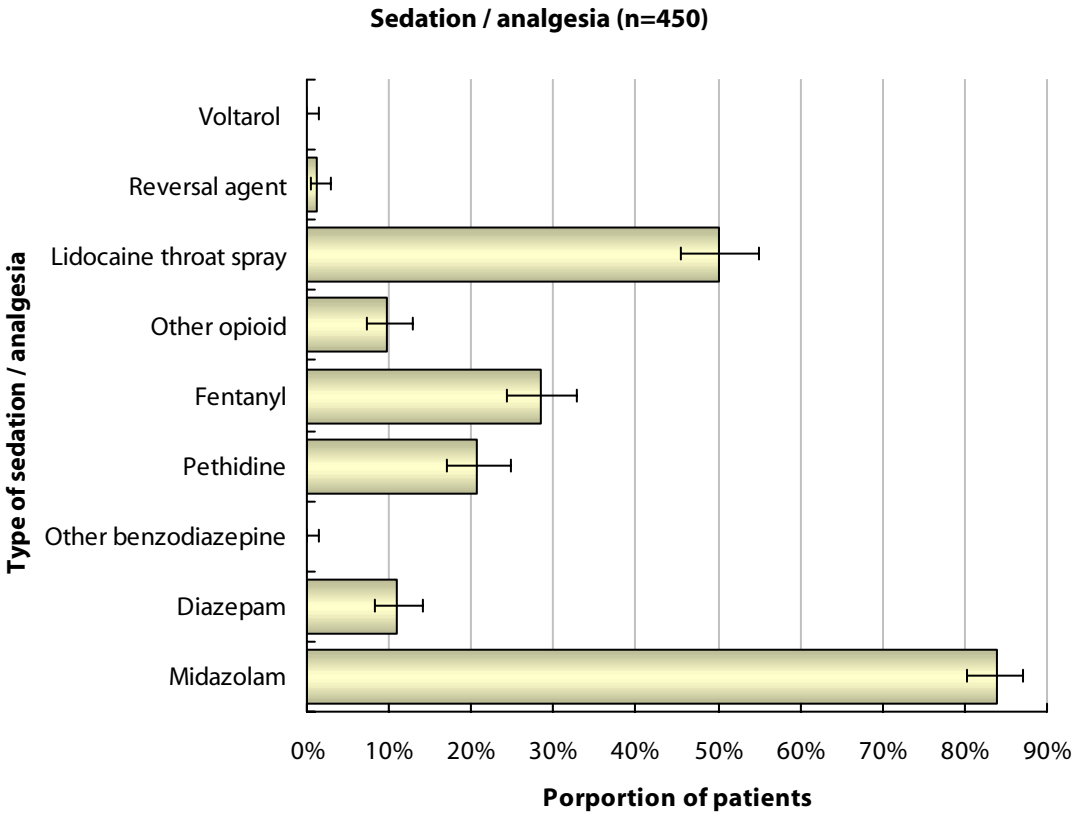
Sedation

96% of patients received intravenous sedation and 59% of patients received opioid analgesics; surprisingly only 50% of patients were recorded as receiving Lidocaine throat spray. Patients not having their throat anaesthetised are more likely to require higher levels of sedation. Topical anaesthesia should be used routinely.

Hypnotics: Midazolam is more widely used than Diazepam due to its quicker onset of action and much shorter half-life.

Opiates: Fentanyl is preferable to other opioids due to its better analgesic effect, quicker onset of action, shorter half-life and lower risk of inducing nausea and vomiting.

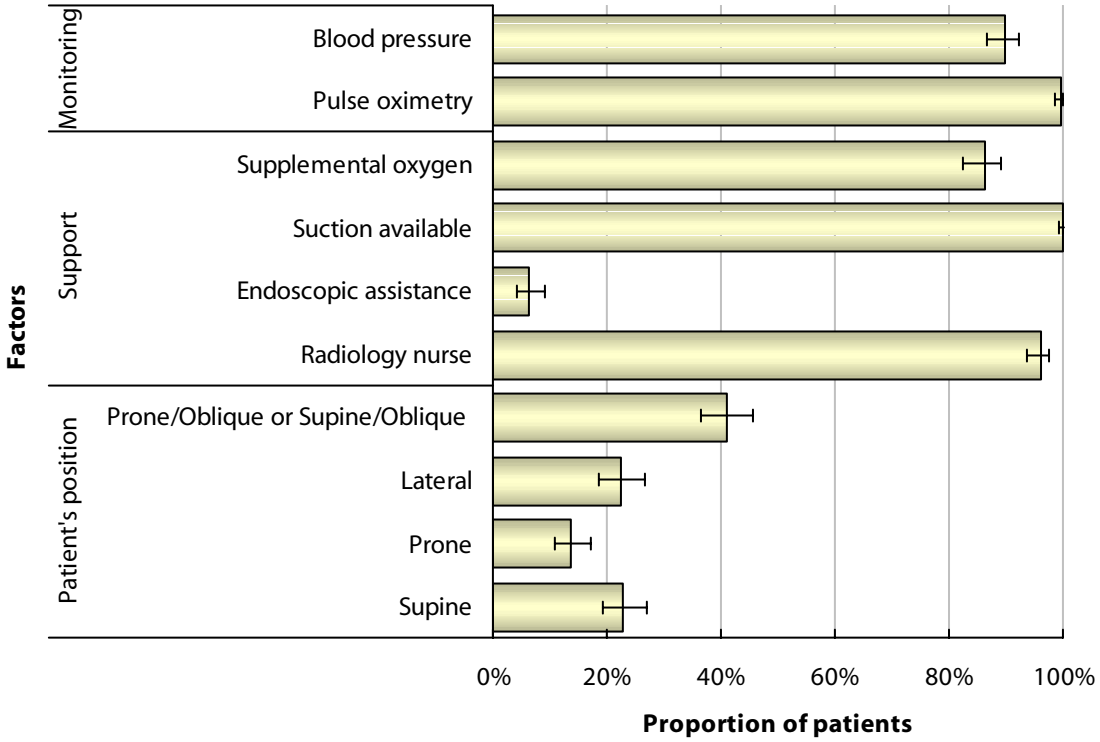
Reversal agents were only required in a very small proportion of patients suggesting an overall appropriate level of sedation.



Other procedure details

All patients were monitored using pulse oximetry, most patients received additional blood pressure monitoring; however 15% of patients were sedated without supplemental oxygen. Patient positioning was very variable.

Patient-position, support and monitoring during the procedure



Stent used

Despite changes in licencing and the availability of removable and valved stents, the most frequently used stent was the Flamingo Wallstent followed by the covered Ultraflex, which reflects operator preference and the lack of comparative data on different stents. Only 36% of patients received a removable stent.

Although two thirds of patients had tumours close to the gastro-oesophageal junction only one in five were treated with an anti-reflux stent.

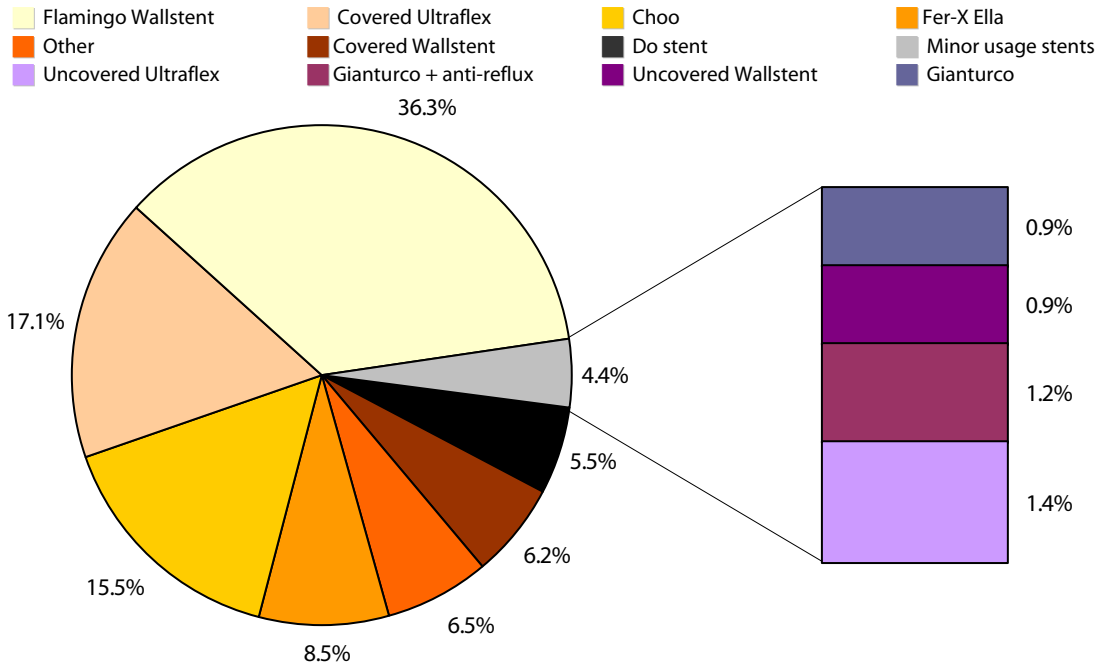
Removable and valved stents are being underused. A large variety of removable stents with different characteristics are now available suitable for any type of stricture and anatomical location. Being able to reposition or remove the stent increases the options for managing stent complications as well as allowing temporary stenting prior to definitive treatment.

While there is increasing evidence on the benefits of anti-reflux stents, there are no reports on adverse effects of their use.

[N]=Nitinol; [R]=Removable; [V]=Valve

Stent placed	
Choo [NR]	67
Covered Ultraflex [N]	74
Covered Wallstent	27
Do stent [NRV]	24
Fer-X Ella [RV]	37
Flamingo Wallstent	157
Gianturco	4
Gianturco + anti-reflux valve [V]	5
Other	28
Uncovered Ultraflex [N]	6
Uncovered Wallstent	4

Stent used; single stent placement only (n=433)



Stent used by hospital

There is great variation in practice in terms of choice of stent device between hospitals, as shown by the table below. This variation probably reflects the lack of comparable data between the use of different stents.

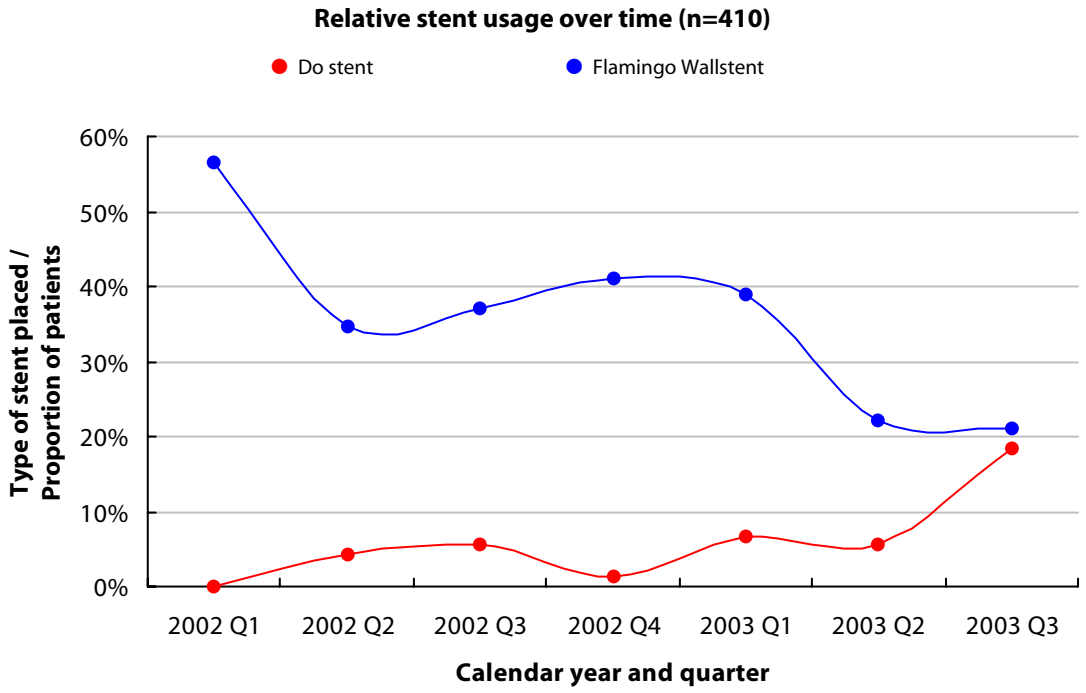
Infrequently used stents (used in less than 5% of cases) are presented as *Others*.

Hospital	Stent placed						
	Choo	Covered Ultraflex	Covered Wallstent	Do stent	Fer-X Ella	Flamingo Wallstent	Others
Chorley & District Hospital	1	0	9	0	0	25	1
Conquest Hospital, Hastings	0	1	0	0	0	10	0
Eastbourne District General Hospital	30	0	0	0	2	8	5
Falkirk Royal Infirmary	0	3	1	0	0	0	2
Frimley Park Hospital	0	32	0	0	0	0	10
Gartnavel General Hospital	0	7	1	0	0	12	0
Hairmyres Hospital	8	0	0	1	1	0	0
John Radcliffe Hospital	2	1	1	0	0	9	0
Kings Mill Hospital	0	2	0	0	0	7	2
Musgrove Park Hospital	0	4	0	0	2	30	0
Nottingham City General Hospital	0	4	0	0	4	9	2
Queen Elizabeth Hospital	0	6	1	0	1	2	0
Royal Glamorgan Hospital	0	7	0	2	3	5	2
Sandwell Hospital	0	0	14	0	0	22	13
South Manchester University Hospital	25	0	0	21	24	4	10
South Tyneside District Hospital	0	7	0	0	0	14	0
Southmead Hospital	1	0	0	0	0	0	0
All	**67**	**74**	**27**	**24**	**37**	**157**	**47**

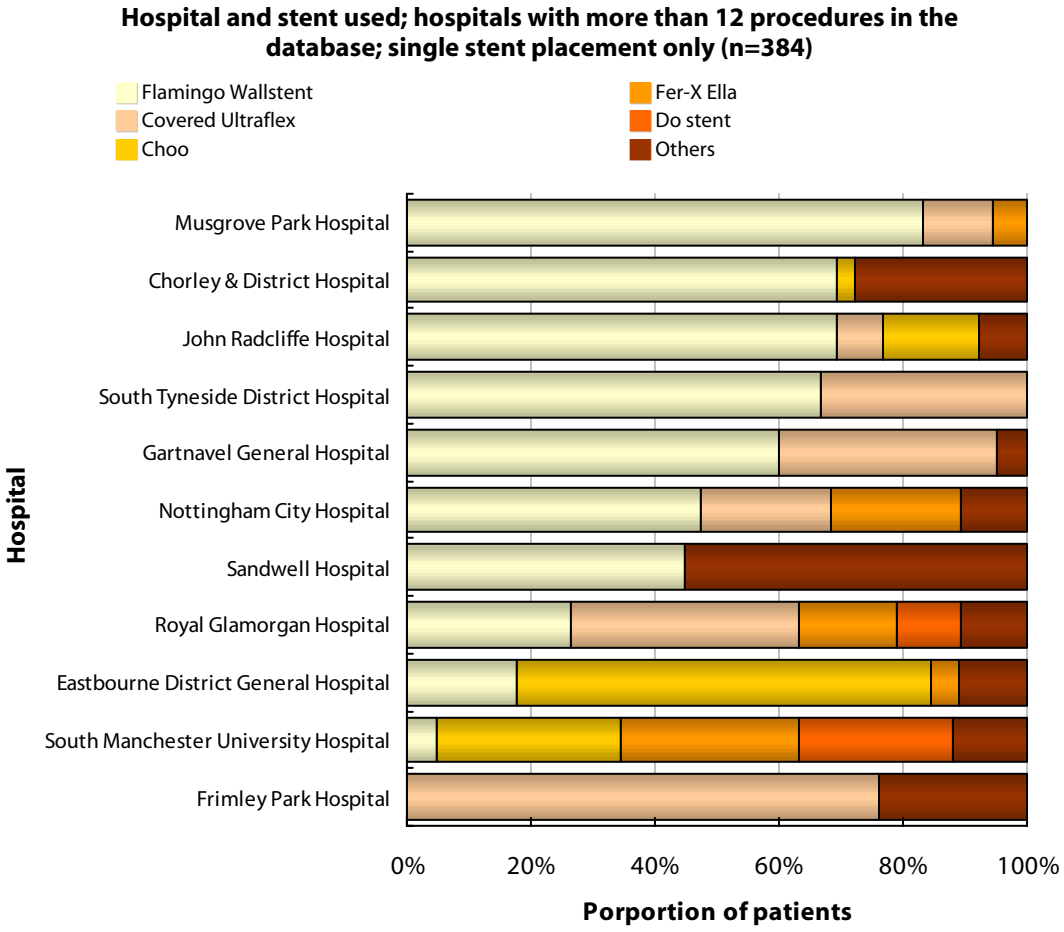
Use of stents over time

During data-acquisition, several stent models were introduced or modified; instruction on usage for some stents also changed.

The graph illustrates the reduction in use of one of the most popular devices (Flamingo Wallstent) with the introduction of removable and valved stents. Several devices were introduced or modified during the time of data collection and the results have to be considered in this context.



Most centres used only one or two different stents for the majority of their procedures.



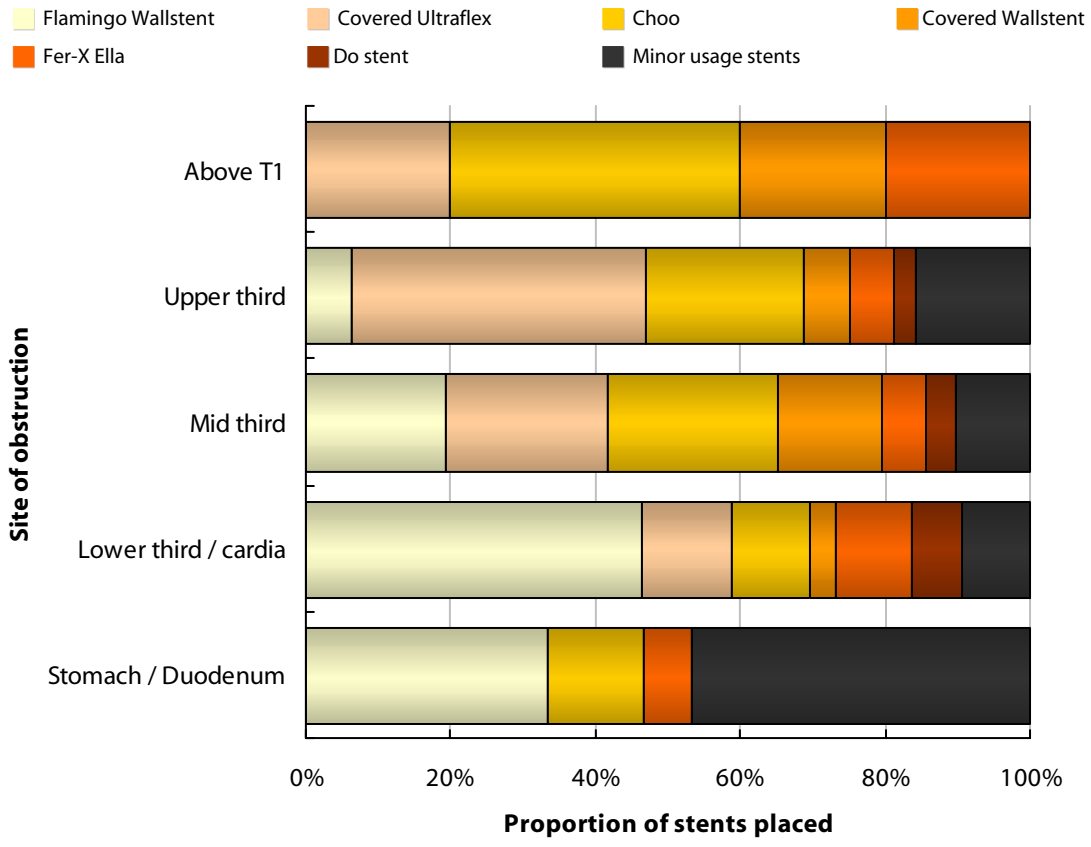
Stent used and site of obstruction

The Flamingo Wallstent remains one of the most popular devices, however practitioners should be reminded that since 2001 this device is only licenced for placement in the lower oesophagus.

The majority of radiologists still seem reluctant to use valved stents at the gastro-oesophageal junction despite the emerging evidence that there is significant benefit to the patient.

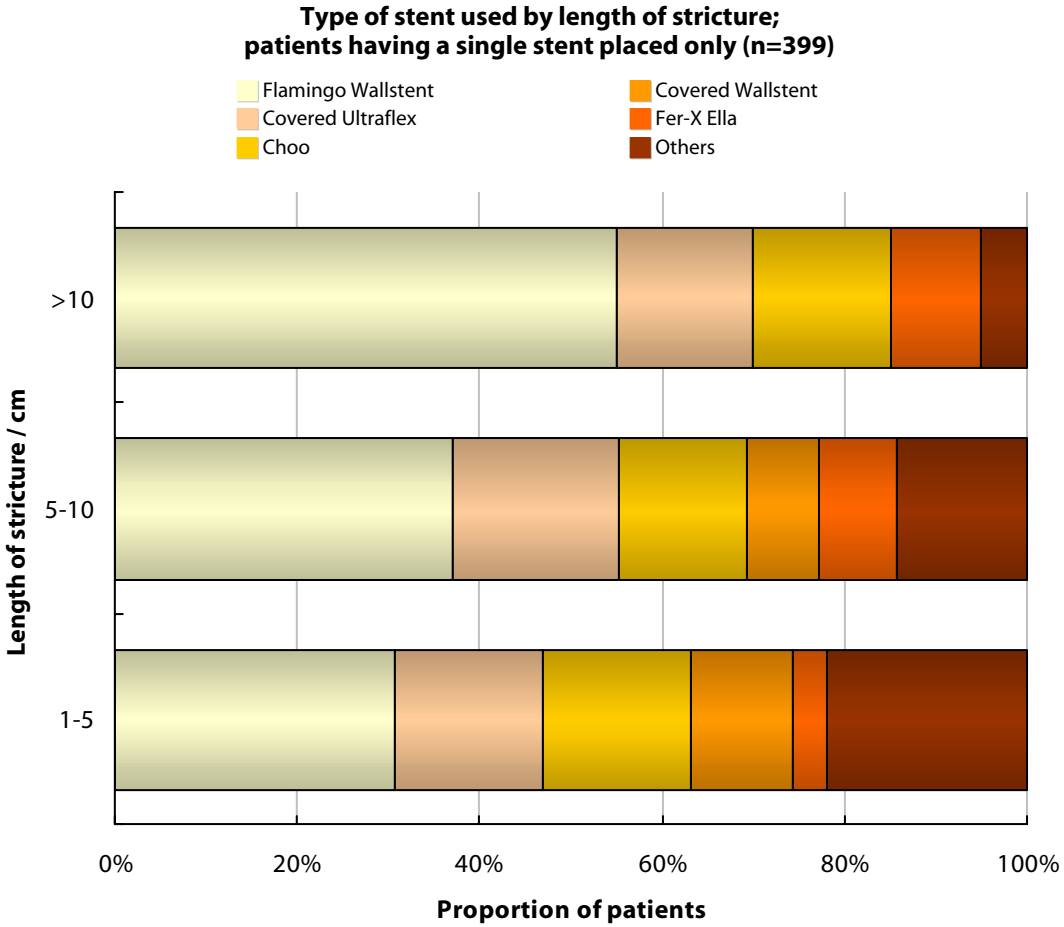
		Stent placed							
		Un-valved-stent				Valved stents			
		Choo	Covered Ultraflex	Covered Wallstent	Flamingo Wallstent	Minor usage	Fer-X Ella	Do stent	Gianturco + anti- reflux
Site of obstruction	Above T1	2	1	1	0	0	1	0	0
	Upper third	7	13	2	2	5	2	1	0
	Mid third	23	22	14	19	10	6	4	0
	Lower third / cardia	29	34	10	125	20	28	19	5
	Stomach / Duodenum	2	0	0	5	7	1	0	0
	Unspecified	4	4	0	8	0	0	0	0

Stent used by site of obstruction; single stent placement only (n=415)



Stent used and length of stricture

There was a clear preference for the Flamingo Wallstent for longer strictures. This is surprising as the Flamingo has a maximum length of 15 cm, whereas several other stents with similar pullback delivery systems are available longer than this.

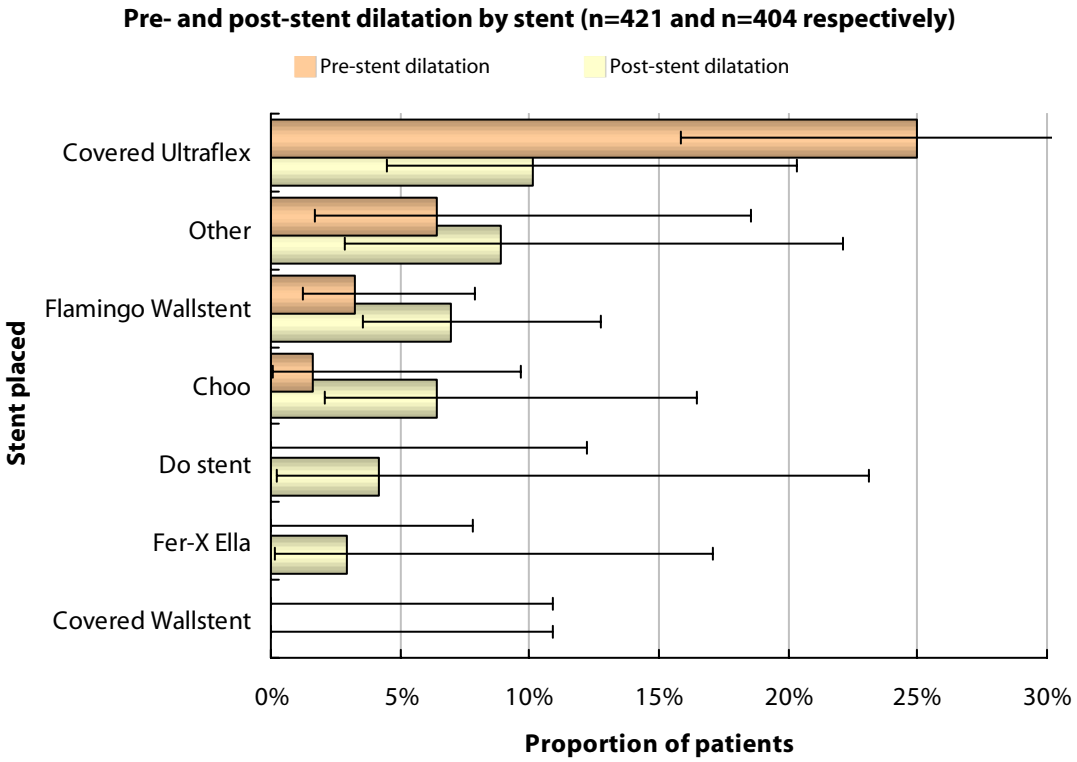


Pre- and post-stent dilatation

Pre-dilatation was performed in 21/80 (26%) procedures using an Ultraflex stent. It is not clear whether this was performed routinely by a few operators or reflects the difficulties of passing the string-retaining delivery system through the stricture. The manufacturer only recommends dilatation of strictures that are too tight for passing the delivery system.

9/80 (11%) Ultraflex stents were also dilated after deployment. The high rate of post-deployment dilatation with the Flamingo Wallstent is surprising, as woven stainless steel stents are perceived to have a higher immediate expansion rate. This may however reflect individual practice. Operators should bear in mind that stents will continue to expand over several days and that the initial appearance is not necessarily a predictor of the final diameter.

		Timing of dilatation					
		Pre-stent			Post-stent		
		No	Count / Rate Yes	Unspecified	No	Count / Rate Yes	Unspecified
Stent placed	Choo	62	1 1.6%	4	58	4 6.5%	5
	Covered Ultraflex	54	18 25.0%	2	62	7 10.1%	5
	Covered Wallstent	26	0 0.0%	1	26	0 0.0%	1
	Do stent	23	0 0.0%	1	23	1 4.2%	0
	Fer-X Ella	37	0 0.0%	0	33	1 2.9%	3
	Flamingo Wallstent	148	5 3.3%	4	134	10 6.9%	13
	Gianturco	4	0 0.0%	0	3	1 25.0%	0
	Gianturco + anti-reflux valve	5	0 0.0%	0	4	1 20.0%	0
	Other	28	0 0.0%	0	26	0 0.0%	2
	Uncovered Ultraflex	3	3 50.0%	0	4	2 33.3%	0
	Uncovered Wallstent	4	0 0.0%	0	4	0 0.0%	0
	All	**394**	**27** **6.4%**	**12**	**377**	**27** **6.7%**	**29**



Minor-usage stents are not displayed individually in this chart.

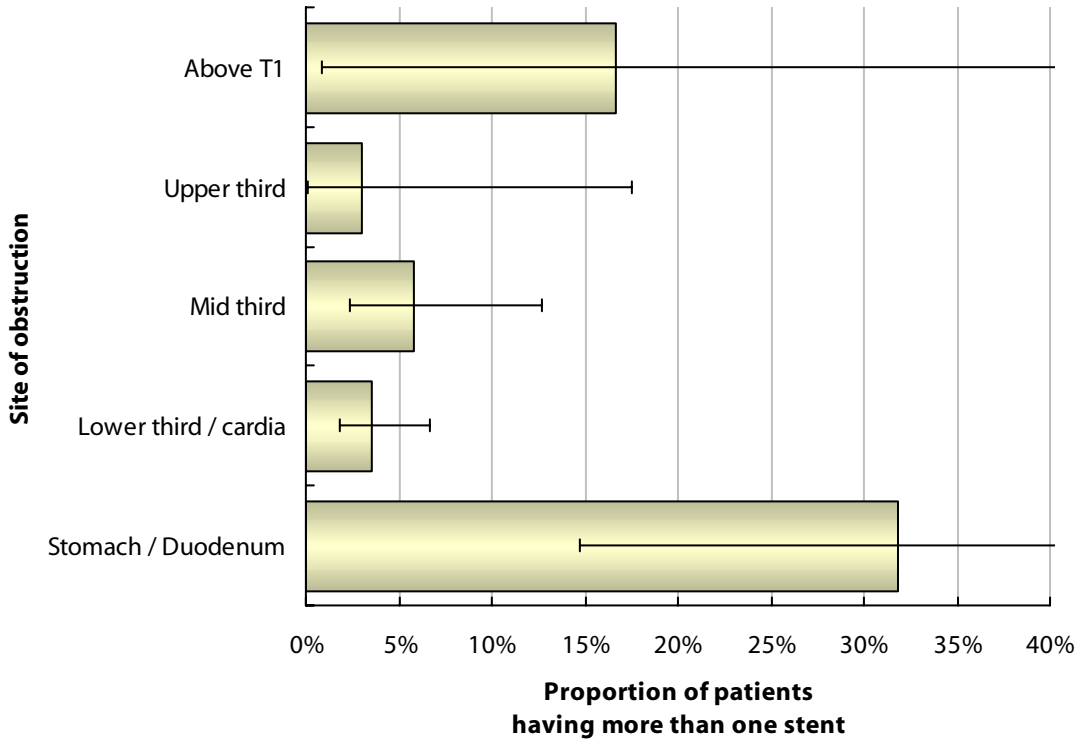
Multiple stent usage

Only a small proportion of patients required the insertion of more than one stent and there was no correlation with the site within the oesophagus itself. More than one stent were required in one-third of procedures involving the stomach and duodenum.

94.4% of strictures in the oesophagus were adequately treated with a single stent (Above T1 – 83.3%; Upper third – 97.0%; Mid third – 94.2%; Cardia – 96.4%). The apparent high rate of procedures requiring more than one stent in the cervical oesophagus is likely to represent sampling error, due to small numbers.

		Number of stents placed			
		Single stent	Two or more stents	Unspecified	**Patient denominator**
Site of obstruction	Above T1	5	1	0	**6**
	Upper third	32	1	0	**33**
	Mid third	98	6	0	**104**
	Lower third / cardia	270	10	1	**281**
	Stomach / Duodenum	15	7	0	**22**
	Unspecified	16	1	1	**18**
	Patient denominator	**433**	**23**	**2**	**458**

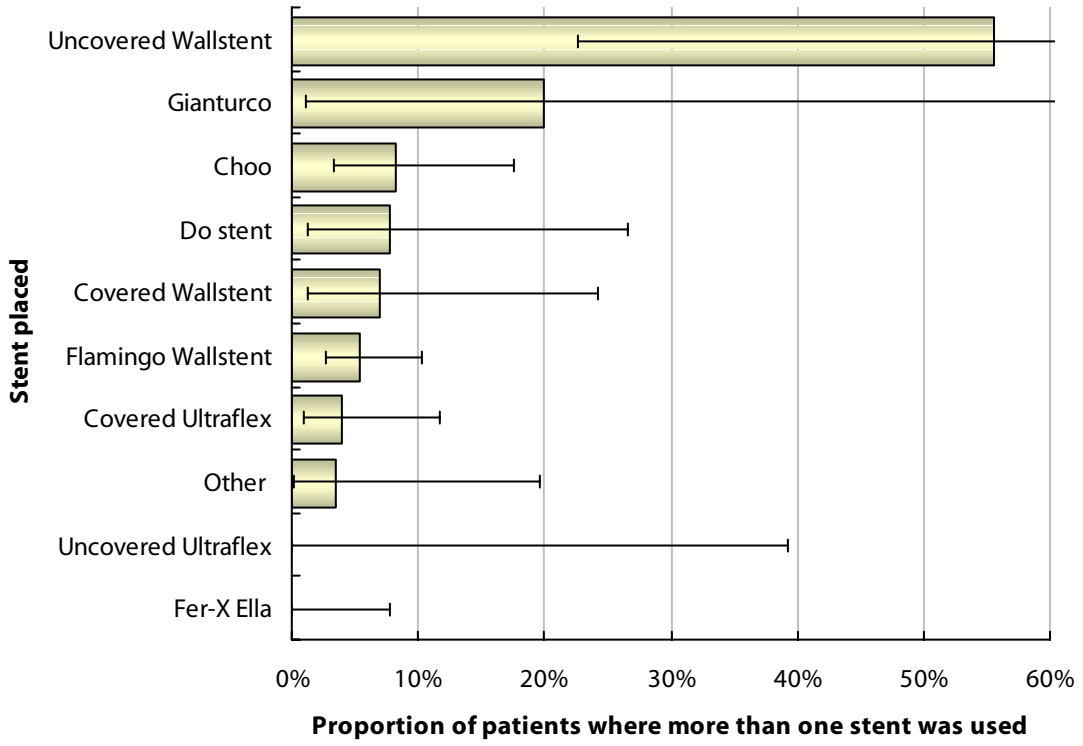
Multiple stent usage and site of obstruction (n= 456 patients; n= 480 stents)



The device most commonly requiring a further stent was the uncovered (Enteral) Wallstent. The maximum available length of this stent is only 9 cm and it is designed for endoscopic use in the small and large bowel.

		Number of stents placed				
		Single	Two identical	Three identical	One with another type	Unspecified
Stent placed	Choo	67	3	1	3	0
	Covered Ultraflex	74	0	0	3	0
	Covered Wallstent	27	1	0	1	0
	Do stent	24	1	0	1	0
	Fer-X Ella	37	0	0	0	0
	Flamingo Wallstent	157	4	0	5	0
	Gianturco	4	0	0	1	0
	Gianturco + anti-reflux valve	5	0	0	1	0
	Other	28	1	0	1	0
	Uncovered Ultraflex	6	0	0	0	0
	Uncovered Wallstent	4	3	0	2	0
	Unspecified	0	0	0	0	1
	Patient denominator	**433**	**13**	**1**	**9**	**0**

Multiple stent usage and stent used (n= 456 patients; n= 480 stents)



Early outcomes

All but one single-stent placements were recorded as being a technical success, giving an overall technical success rate of 99.8%. Deployment of one Flamingo stent at the gastro-oesophageal junction failed.

Early complications

Early complications by device

There is not enough evidence in the literature to confirm that softer stents are more likely to conform to angles as well as peristalsis resulting in a lower migration rate, however case reports on oesophageal perforation and chest pain are virtually limited to large, stiff stents.

The latest generation stents tend to show a reduced incidence of complications compared with the literature. The figures for the Do and Fer-X Ella stents are given as combined figures for the initial and modified versions.

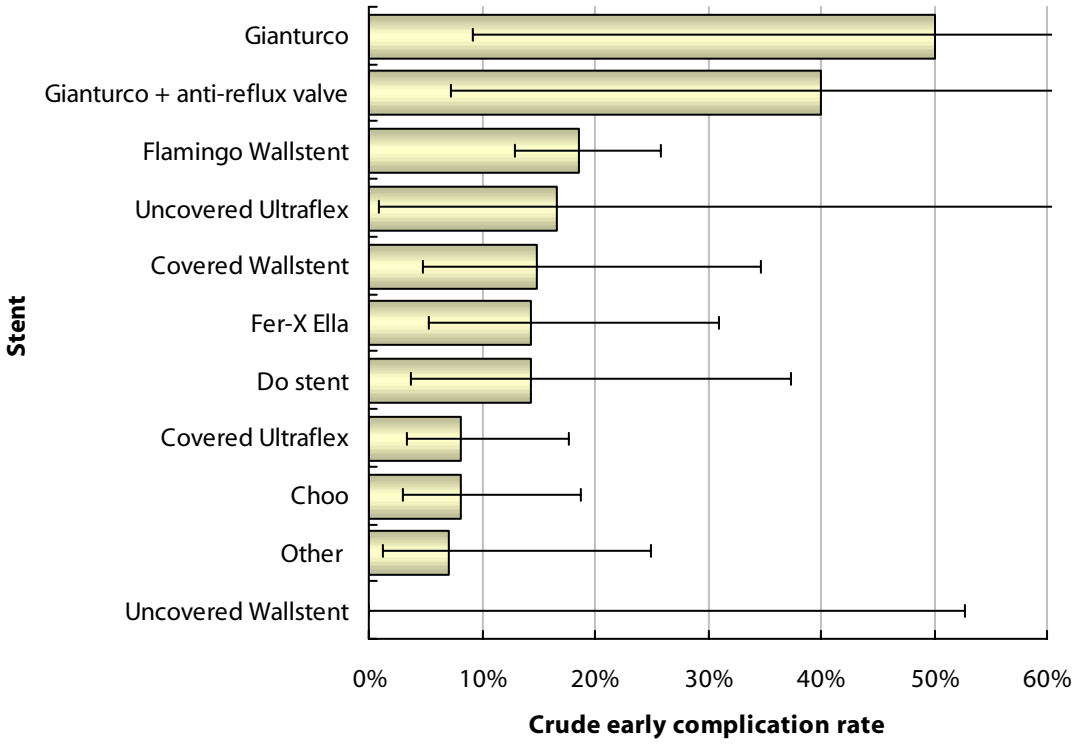
[N]=Nitinol; [SS]=Stainless steel

		Early complications				
		No	Yes	Unspecified	All	Rate where known
Stent placed	Choo [N]	56	5	6	**67**	8.2%
	Covered Ultraflex [N]	67	6	1	**74**	8.2%
	Covered Wallstent [SS]	23	4	0	**27**	14.8%
	Do stent [N]	18	3	3	**24**	12.5%
	Fer-X Ella [SS]	30	5	2	**37**	14.3%
	Flamingo Wallstent [SS]	127	29	1	**157**	18.6%
	Gianturco [SS]	2	2	0	**4**	50.0%
	Gianturco + anti-reflux valve [SS]	3	2	0	**5**	40.0%
	Other	26	2	0	**28**	7.1%
	Uncovered Ultraflex [N]	5	1	0	**6**	16.7%
	Uncovered Wallstent [SS]	4	0	0	**4**	0.0%
	All	**361**	**59**	**13**	**433**	**14.0%**

Note that early complications were not recorded for 13 patients. This illustrates the difficulty in recording outcome data for 100% of patients.

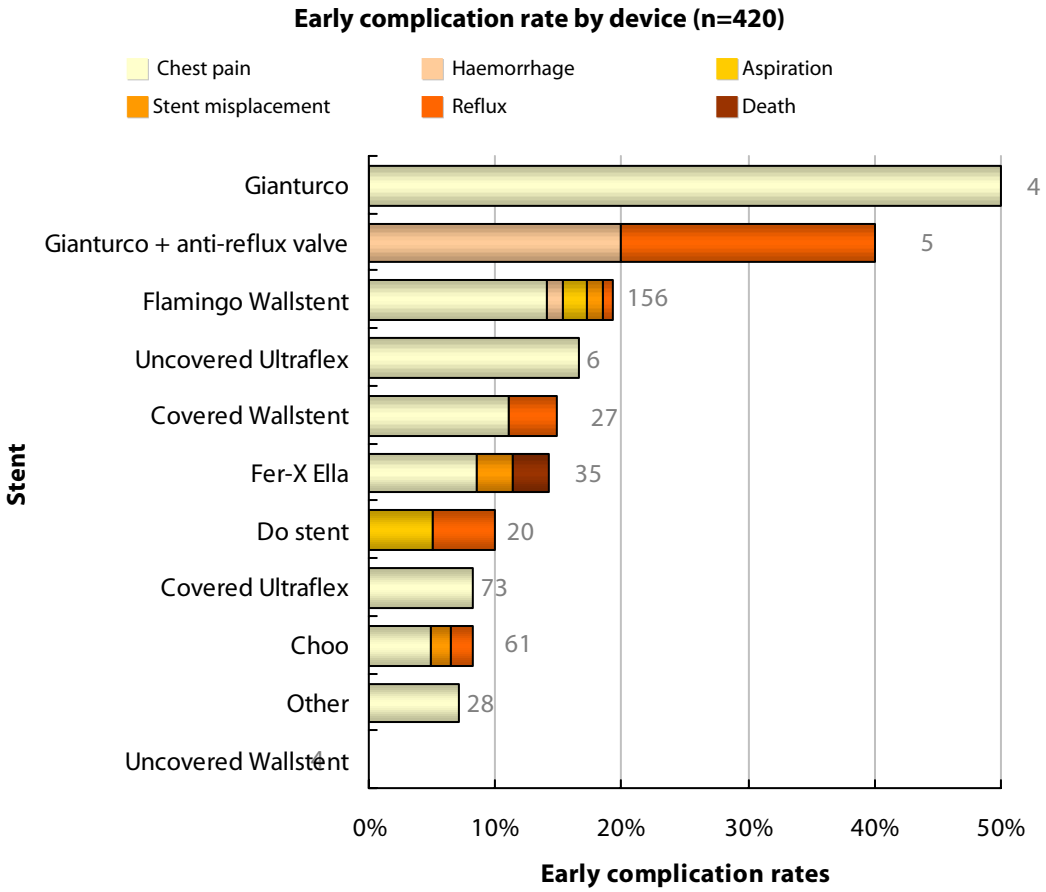
At first glance the complication rates vary widely between devices; however, given the small numbers and the overlapping confidence intervals, more data are required to confirm or refute these apparent differences.

Early complication rate by device (n=420) [vi]



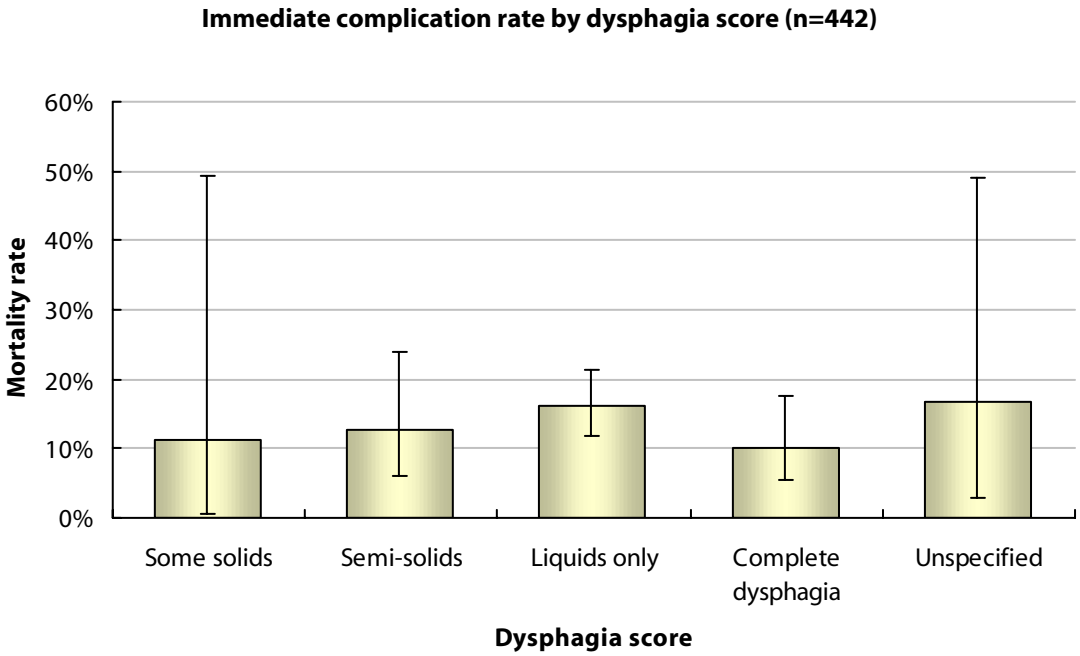
[vi] Single stent placement only

Chest pain is by far the most common complication. The early, post-procedural mortality rate was 0.2%. There were no reported instances of perforation as an early complication.



Early complications by dysphagia

The degree of dysphagia at the time of stenting did not have any great effect on complication rate.



Early complications funnel plots

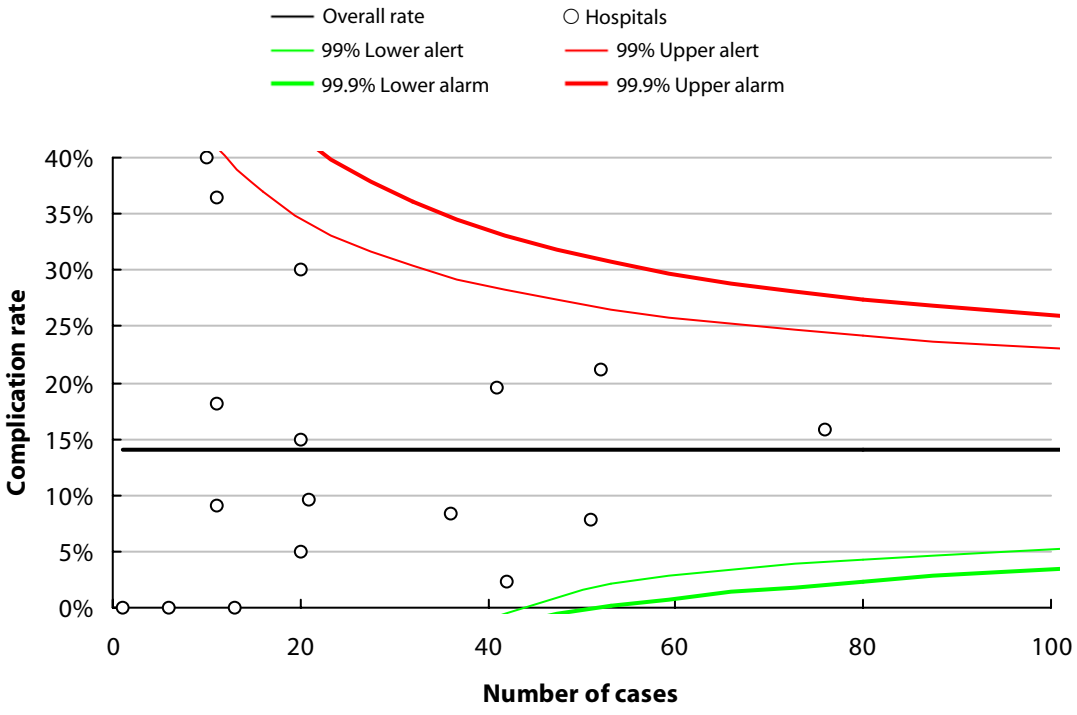
Shewhart control charts have been suggested as a means of presenting performance indicator results in the healthcare setting without having to resort to spurious ranking into *league tables* [15,16]. These plots show observed number of events against volume of cases on a square root scale; unfortunately this format appears unintuitive, obscures the observed event rates, and leads to rather approximate control limits. Applying a small adjustment – plotting the event rates against volume of cases – leads to the so-called *funnel plot*, which is widely used in meta-analyses to check for publication bias [17] and has also been used to compare mortality rates in other specialties [18]. Exact binomial control limits around the overall event rate are superimposed to indicate possible thresholds for *alert* and *alarm* respectively.

Funnel plots discourage inappropriate ranking while providing a strong visual indication of *divergent* performance or *special cause* variation. Advantages over the Shewhart control chart approach include the display of the observed event rates, an informal check of the relationship between event rate and volume of cases, an emphasis on the increased variability expected from smaller centres, intuitive choice of axes (hence easy plotting) and exact binomial control limits easily obtainable from the most popular spreadsheet packages.

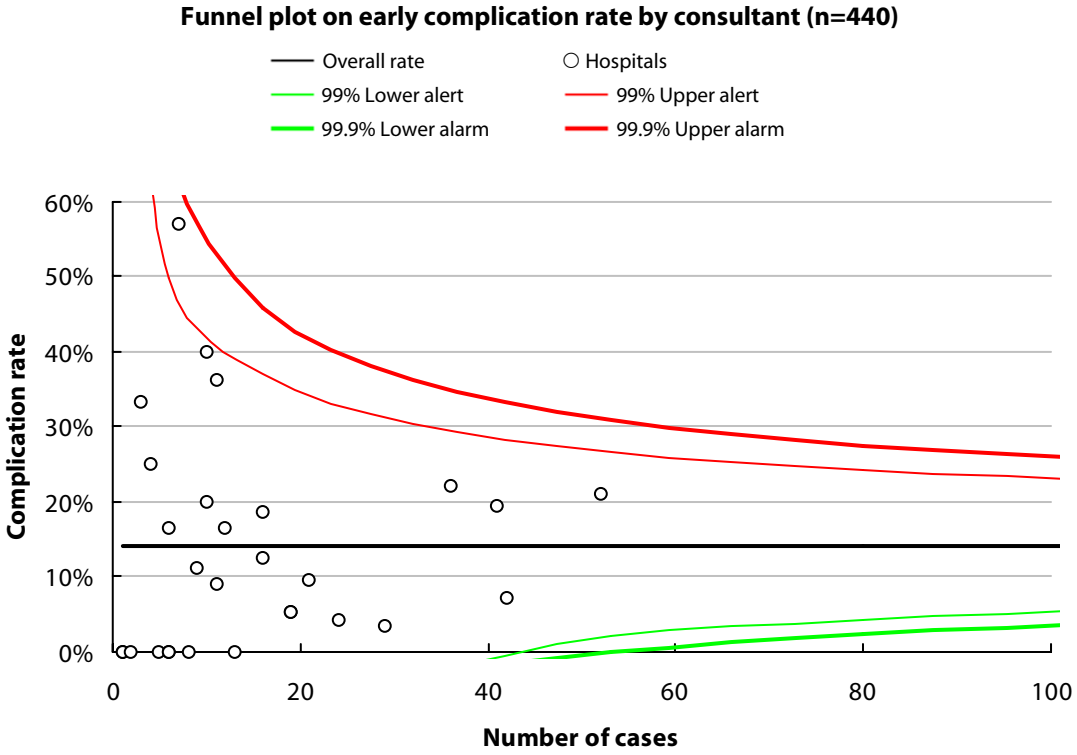
Of course, this analysis is not risk adjusted, and therefore has all the problems associated with not comparing like with like.

The average early complication rate was 14%. No hospital's nor any consultant's early complication rate fell outside the alarm limits used in these charts; the relatively-high and relatively-low early complication rates are associated with low-volume centres as one might expect from a statistical perspective.

Funnel plot on early complication rate by hospital (n=442)



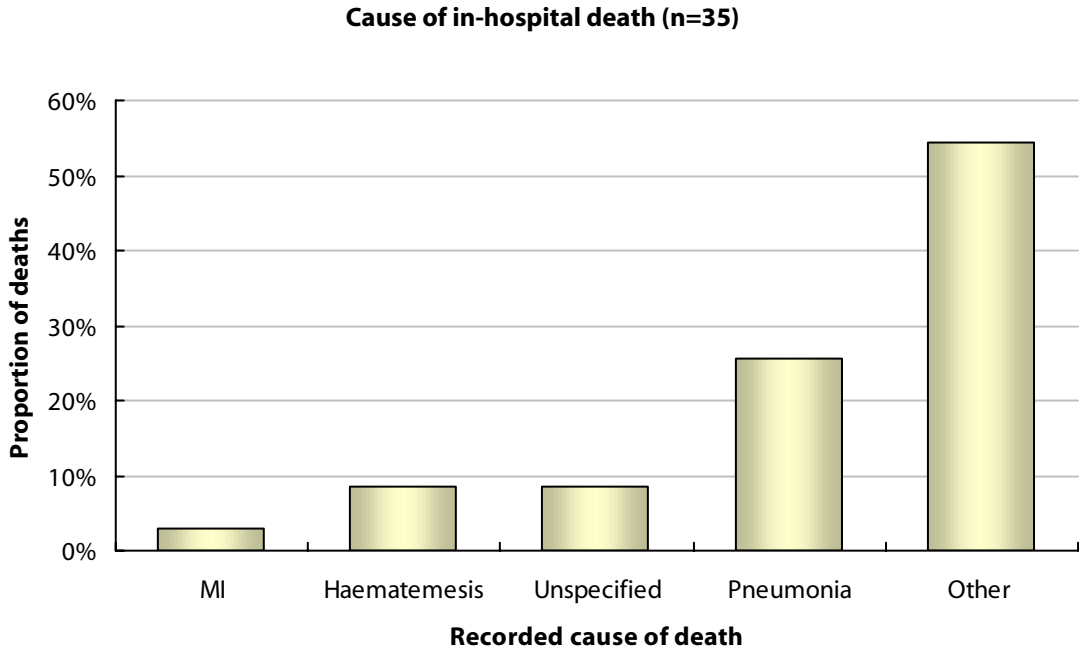
All but one consultant fell between the upper and lower alert lines. One consultant had an observed complication rate of 57% (overall n=7; complications: 2 with chest pain and 2 with aspiration), which is outside the upper alert line, but within the upper alarm line. It is difficult to comment to what degree the events observed are related to radiological techniques or the device itself. Risk modelling methodology, when available, would help clarify this for future registries.



In-hospital death

Cause-of-death

The overall in-hospital mortality rate was 9.2%, of which the majority were not stent-related. Cause-of-death was assessed by location of tumour, stent and dysphagia score and no clear relationships were found.

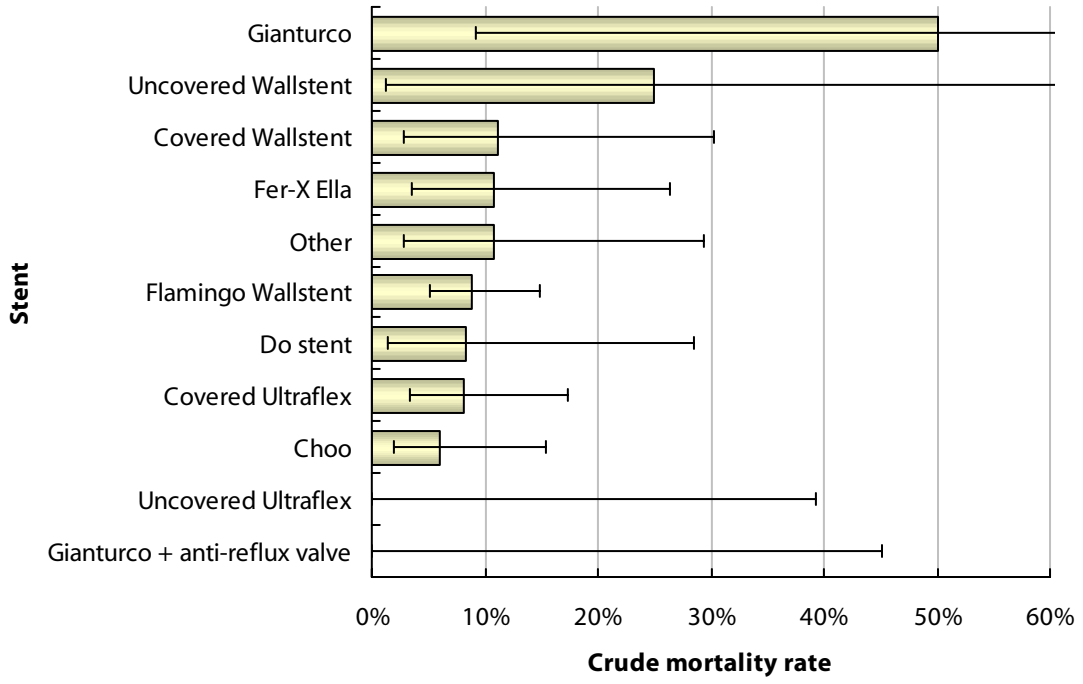


In-hospital mortality by device

As with the complication rate, mortality seemed to be higher when stiffer stents were used, but no statistically significant differences were detected; causes of death were not obviously procedure-related.

		Mortality			
		No	Yes	Unspecified	All
Stent placed	Choo	63	4	0	**67**
	Covered Ultraflex	68	6	0	**74**
	Covered Wallstent	24	3	0	**27**
	Do stent	22	2	0	**24**
	Fer-X Ella	33	4	0	**37**
	Flamingo Wallstent	143	14	0	**157**
	Gianturco	2	2	0	**4**
	Gianturco + anti-reflux valve	5	0	0	**5**
	Other	25	3	0	**28**
	Uncovered Ultraflex	6	0	0	**6**
	Uncovered Wallstent	3	1	0	**4**
	All	**394**	**39**	**0**	**433**

Early mortality rate by stent (n=433) [vii]

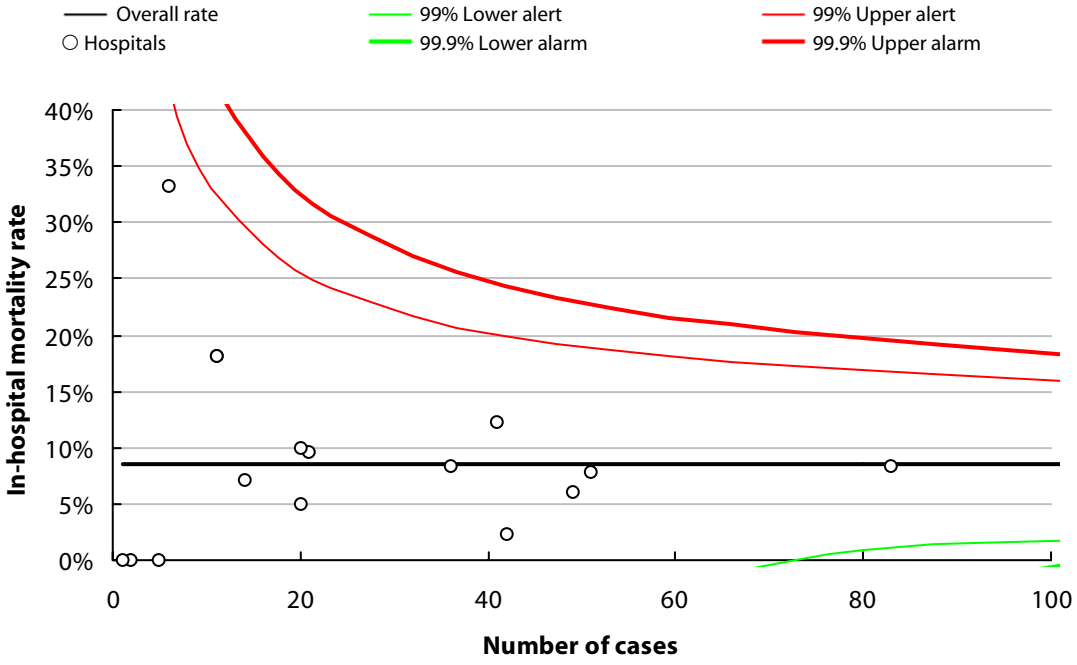


[vii] Single stent placement only

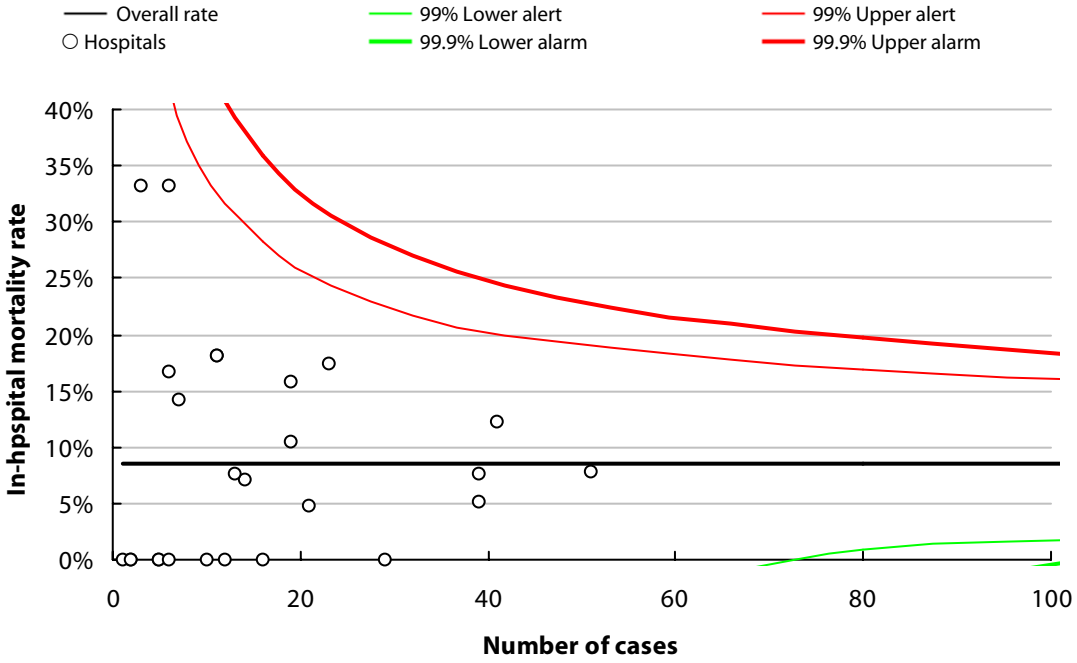
In-hospital mortality funnel plots

Apparently-high and apparently-low mortality rates were associated with low numbers of cases. There were no significant outliers for mortality by hospital or by consultant.

Funnel plot on mortality rate by hospital (n=413)



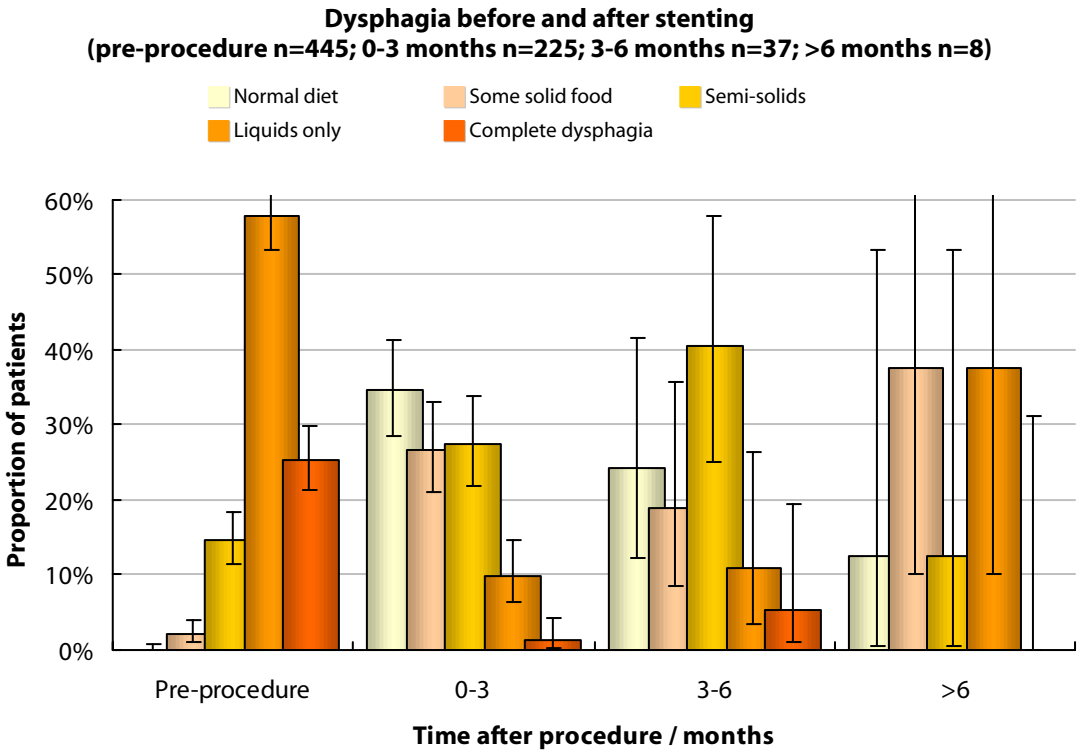
Funnel plot on mortality rate by consultant (n=411)



Long-term follow up

Dysphagia

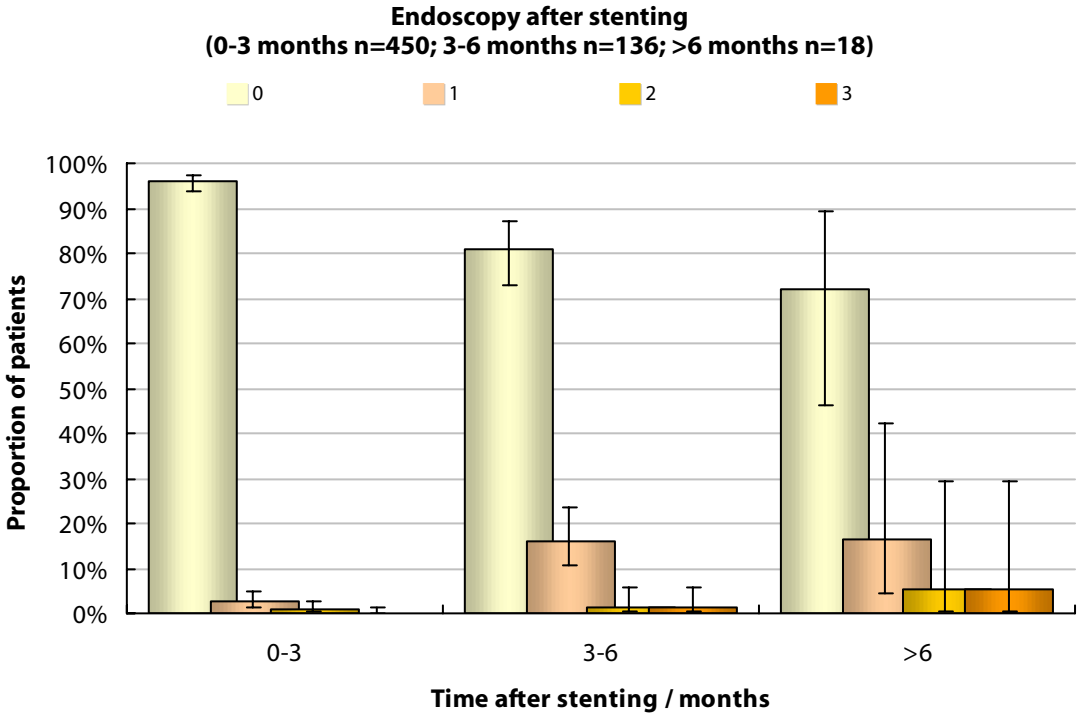
The median dysphagia score prior to stenting was 3 (liquids only), improving to 1 (some solids) immediately after stenting. The majority of patients (88.9% at 0-3 months; 83.8% at 3-6 months; 62.5% at >6 months) could eat at least a semi-solid diet until death.



Endoscopy

Recurrent dysphagia requiring re-intervention occurred mostly after a period of 6 months.

As might be expected, the likelihood of dysphagia recurring increases with time. The graph shows the frequency of endoscopy per 3-month interval; 52 patients (11.3% of all patients stented) had at least one endoscopy at some stage following stent insertion.



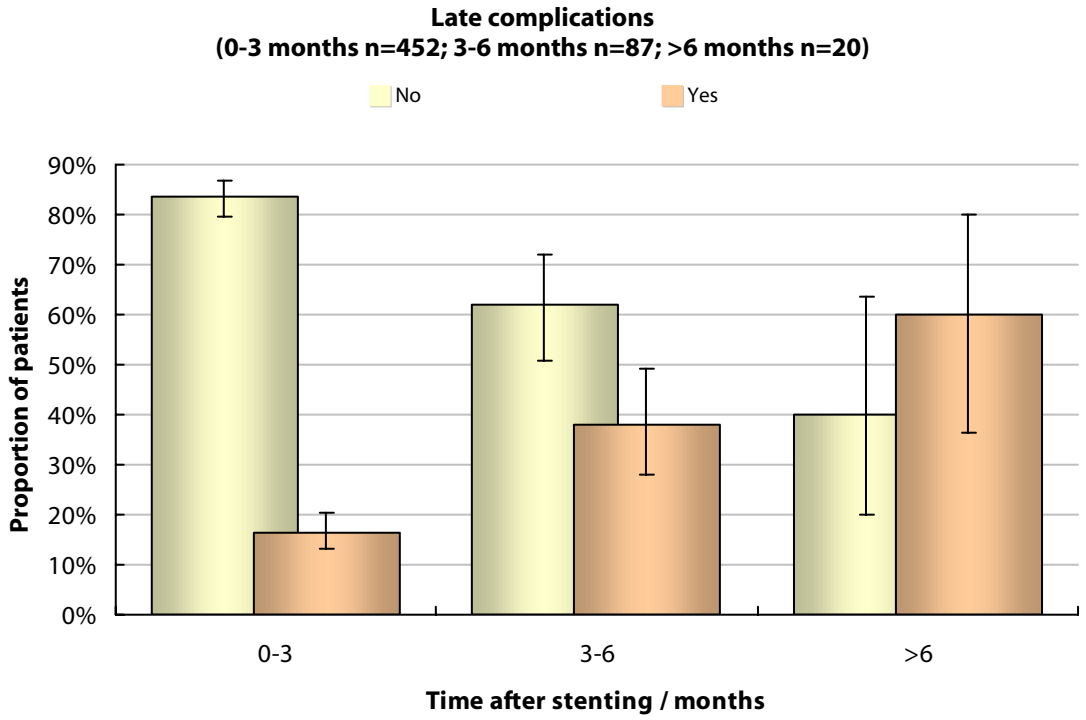
Late complications

Late complications overview

37.9% of patients had complications within the first 6 months; this highlights the need of close follow-up.

60% of patients surviving longer than 6 months had developed a late complication. A dedicated point of contact for the patient is vital.

		Time period after stent placement / months					
		0-3		3-6		>3	
Late complication	None reported	377	83.4%	54	62.1%	8	40.0%
	Stent migration	17	3.8%	7	8.0%	2	10.0%
	Pain	22	4.9%	8	9.2%	2	10.0%
	Reflux	13	2.9%	6	6.9%	6	30.0%
	Haemorrhage	14	3.1%	4	4.6%	0	0.0%
	Tumour overgrowth	8	1.8%	8	9.2%	1	5.0%
	Tumour ingrowth	1	0.2%	3	3.4%	1	5.0%
	Other	12	2.7%	2	2.3%	1	5.0%



Stent migration and device

Excluding devices with low numbers of recorded stent placements, the stent with the lowest migration rate was the Flamingo Wallstent. This is conical in shape and the covering membrane is attached to the inside of the stent mesh. Stent migration remains a problem for anti-reflux stents placed across the gastro-oesophageal junction.

Surprisingly a large proportion of migration occurred after three months. This probably reflects reduction of tumour bulk by chemo- and radiotherapy and again illustrates the need for patient follow-up.

The incidence of migration is given for single initial stent placement only.

		Time period after stent placement / months					
		0-3		3-6		>6 months	
		No	Yes	No	Yes	No	Yes
Stent placed	Choo	64	2 3.0%	10	2 16.7%	2	0 0.0%
	Covered Ultraflex	69	4 5.5%	12	0 0.0%	2	0 0.0%
	Covered Wallstent	27	0 0.0%	7	0 0.0%	3	0 0.0%
	Do stent	20	4 16.7%	8	0 0.0%	0	0 NA
	Fer-X Ella	34	3 8.1%	9	2 18.2%	1	0 0.0%
	Flamingo Wallstent	151	3 1.9%	25	2 7.4%	4	1 20.0%
	Gianturco	4	0 0.0%	0	0 NA	0	0 NA
	Gianturco + anti-reflux valve	5	0 0.0%	2	0 0.0%	0	0 NA
	Other	27	1 3.6%	5	1 16.7%	3	1 25.0%
	Uncovered Ultraflex	6	0 0.0%	1	0 0.0%	2	0 0.0%
	Uncovered Wallstent	4	0 0.0%	0	0 0.0%	0	0 NA
	All	**411**	**17** 4.0%	**79**	**7** 8.1%	**17**	**2** 10.5%

No definite conclusions should be drawn from these figures as the individual numbers of devices used varied considerably and the dataset did not differentiate between stents placed with the lower end above and below the gastro-oesophageal junction.

Stent migration and site of obstruction

The high observed rate of migration in the cervical oesophagus is likely to represent sampling error due to small numbers. Stents placed in the lower third include stents sited across the gastro-oesophageal junction.

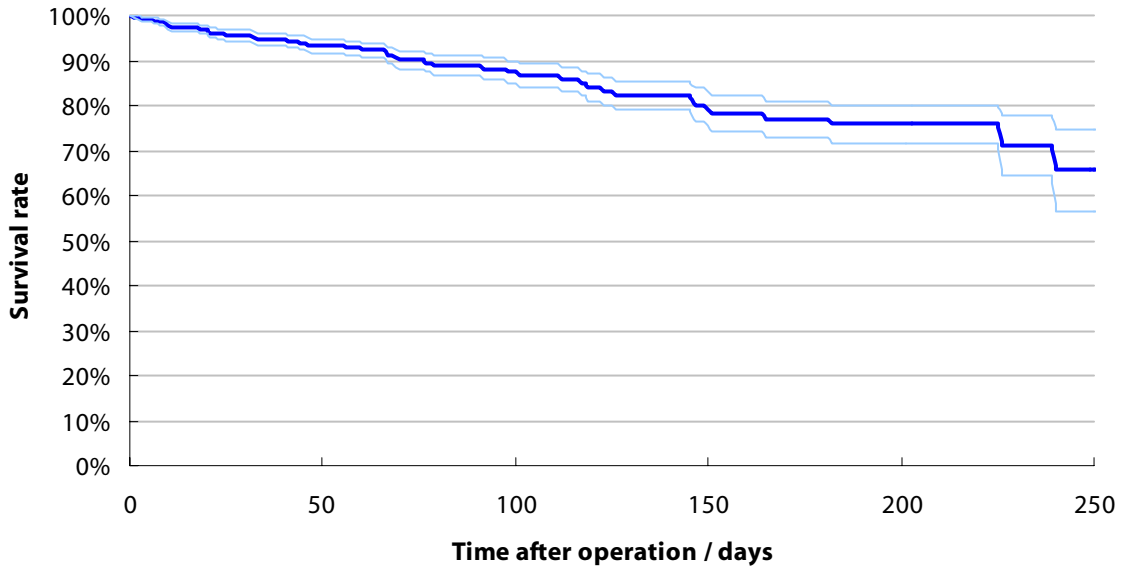
		Time period after stent placement / months					
		0-3		3-6		>6 months	
		No	Yes	No	Yes	No	Yes
Site of obstruction[viii]	Above T1	4	1 20.0%	0	1 100%	0	0 NA
	Upper third	13	1 7.0%	2	0 0.0%	0	0 NA
	Mid third	93	1 1.1%	18	1 5.3%	5	0 0.0%
	Lower third / cardia	254	11 4.2%	50	4 7.4%	10	2 16.7%
	Stomach / Duodenum	31	1 3.0%	6	0 0.0%	1	0 0.0%

[viii] This uses only *pure* sites *i.e.*, where only one of the question options is selected.

Re-stenting

The majority of patients were palliated successfully with a single stent alone. At the time of 50%-survival 12% of patients had required a further stent.

Kaplan-Meier actuarial event-free analysis; re-stenting after first recorded placement (n=413)

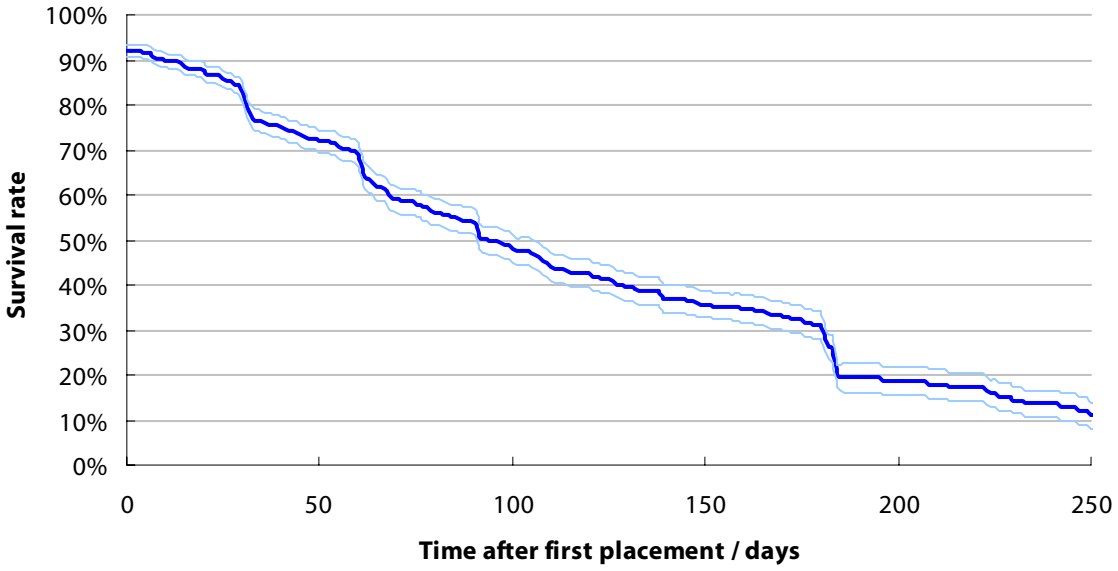


Long-term survival

Overall results

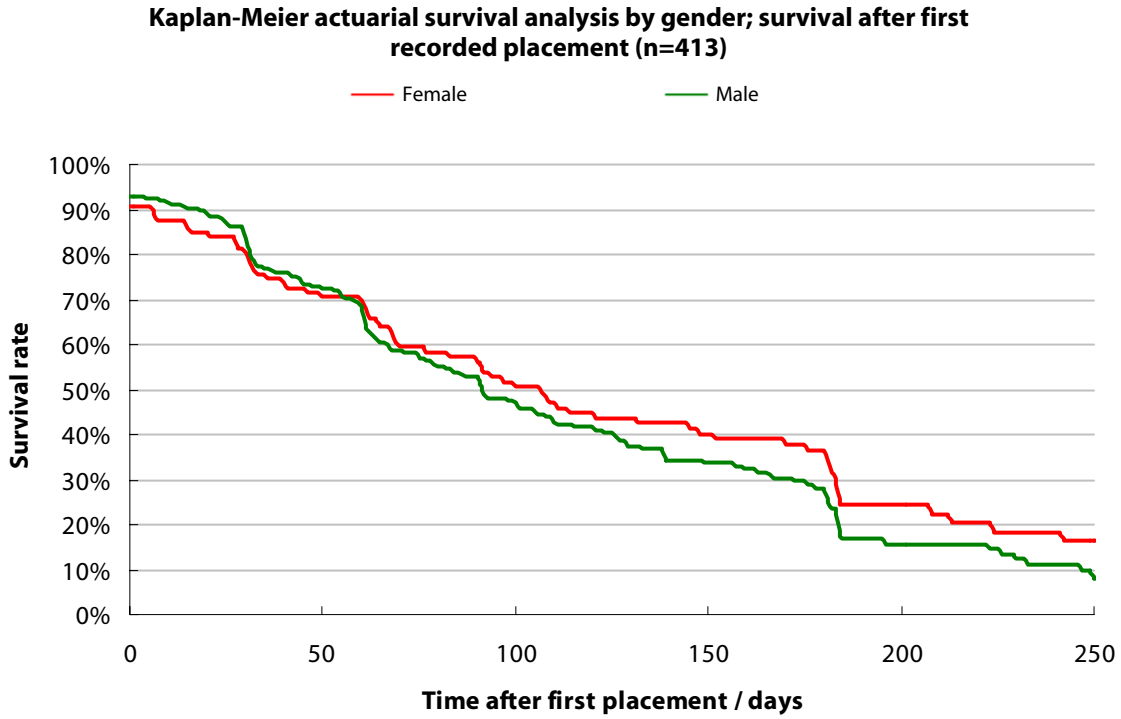
Patients requiring palliative oesophageal stenting have a poor prognosis; 50% of patients had died within 92 days.

Kaplan-Meier actuarial survival analysis; survival after first recorded placement; all entries (n=413)



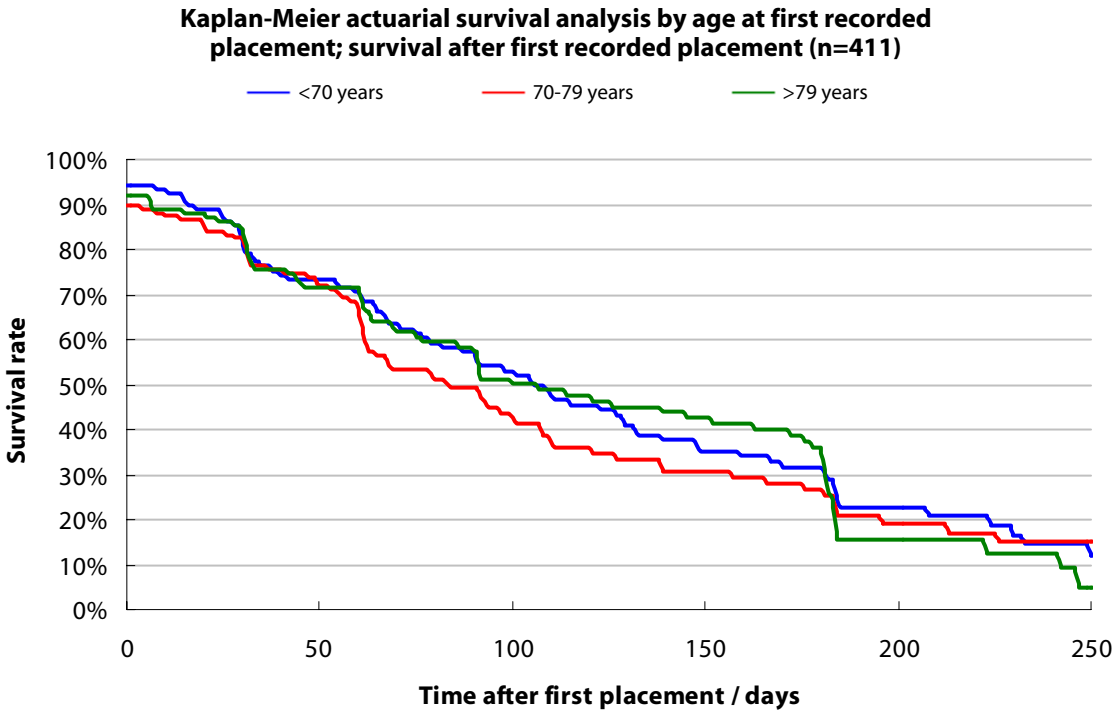
Survival by gender

Women had a marginally better survival than men, although this was not statistically significant.



Survival by age

There was no significant difference in the three age groups analysed.

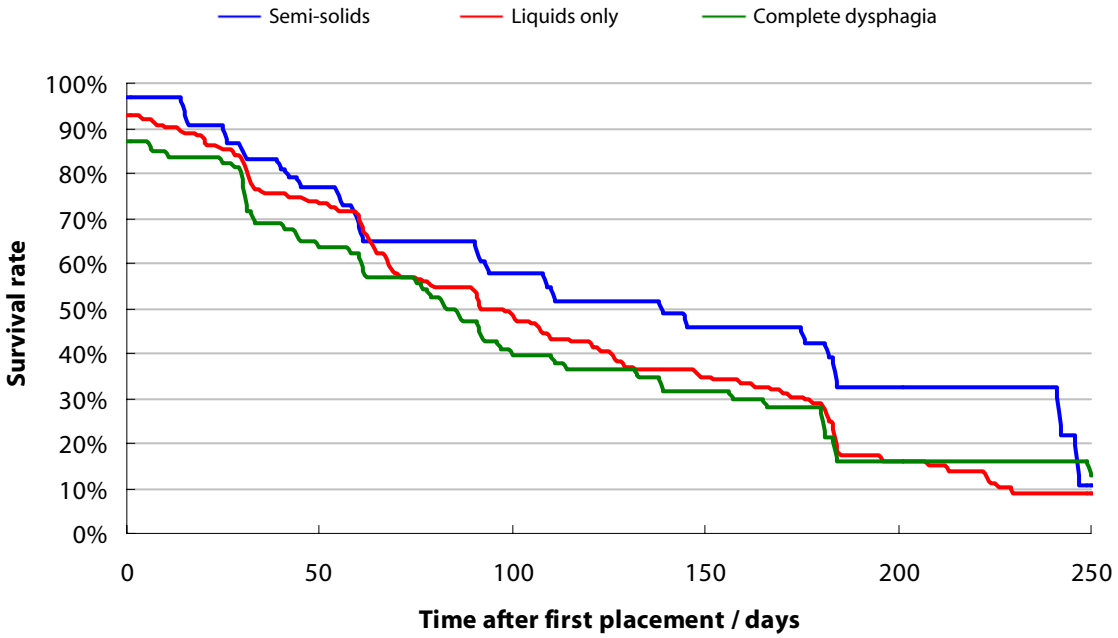


Survival by dysphagia

Patients stented while their dysphagia was of a lower grade seemed to survive longer compared with patients suffering from high-grade dysphagia.

It is however not clear whether this is a truly improved post-stenting outcome or whether these patients were simply stented at an earlier stage within their disease process.

Kaplan-Meier actuarial survival analysis by dysphagia score at first recorded placement; survival after first recorded placement (n=403)



Conclusions

Palliative stenting of oesophageal carcinoma is performed by gastroenterologists, surgeons and radiologists. Although the procedure is well established [19, 20], there is little scientifically robust data on differences between stents and clinical outcome.

With the increasing incidence of adenocarcinoma of the lower oesophagus [21, 22, 23] more stents need to be placed across the gastro-oesophageal junction, which presents particular challenges to the device in terms of migration, chemical resilience and gastro-oesophageal reflux. Unfortunately changes to stent design are often driven by industry competition rather than user requirements and the evidence base is still thin. In vitro studies of new devices are rare [12, 24].

This report shows that data collection for a national database is possible, allowing a large number of patients to be included. However, despite the fact that radiological stent insertion is a common procedure in the UK, only 17 hospitals contributed to the collection of data. Better cooperation is required for the continuation of the ROST database. It is expected that in the future data collection will be possible via the Internet, which will hopefully make the process more user-friendly. However, adequate follow-up of patients remains a particular problem for radiologists who may have to rely on other disciplines to gather appropriate data.

At the time of stent insertion, female patients were more likely to be older than male patients, but less likely to have had previous therapy. The reasons for this are not entirely clear.

Radiological insertion of oesophageal stents is safe and effective. The technical success rate of radiological stenting approached 100% confirming the validity of performing this procedure under fluoroscopy alone. Most stent patients are over 70 years of age and often very frail. Radiological placement is ideal for these patients as it is atraumatic and requires minimal sedation. The main discomfort arises from irritation of the throat, but the data indicate that anaesthetic spray is not used routinely. Adequate throat anaesthesia is likely to reduce the need for sedation. The use of anaesthetic and hypnotic drugs varies widely. In line with the sedation guidelines by the Royal College of Radiologists [3] incremental doses of short-acting drugs (*e.g.* Midazolam, Fentanyl) should be used where required. Careful titration reduces the need for reversal agents. All patients should receive supplemental oxygen, regardless of their pre-procedure oxygen saturation. Levels dropping below 94% require attention and appropriate management.

A large variety of oesophageal stents are being used on the basis of operator preference rather than scientific evidence. The majority of stents placed were older stent designs, foregoing the benefits of newer materials, improved delivery systems and the flexibility offered by dedicated removable and valved stents. Some stents are apparently being used outside their licence on a regular basis.

Covered oesophageal stents are preferable to uncovered stents and the data confirm this to be standard practice. Stent occlusion by tumour in-growth is avoided [25] and the increased risk of migration compared to uncovered stents can be reduced by appropriate stent design [26]. Stent migration remains a problem, occurring in around 10% of patients with tumours at the gastro-oesophageal junction. Newer stent designs have so far not managed to address this particular problem satisfactorily. Migration often occurs after several months and patients, particularly if undergoing further treatment reducing tumour bulk, need to be made aware of this.

Retrievable stents allow stent re-positioning or removal in case of complications, particularly migration [27]. Although there are only few reports of migrated stents causing harm [28], the option of removing a migrated stent from the stomach prior to placing a new stent should be considered.

Inserted on a temporary basis removable stents also allow an aggressive approach to maintaining adequate oral nutrition, while awaiting treatment (*e.g.* radical radiotherapy) or the effects thereof. Temporary stenting of benign strictures is technically feasible [29], but should only be performed by experienced operators as a last resort.

Evidence is emerging on the benefits of using anti-reflux stents across the gastro-oesophageal junction. Regurgitation of gastric content caused by stents placed across the cardia can be severe and debilitating and is greatly reduced by the use of valved stents. Concerns about negative effects of anti-reflux valves have not been substantiated and it is therefore preferable to use a valved stent across the gastro-oesophageal junction, than potentially burden the patient with further oral medication to control reflux symptoms. Unfortunately patients rarely indicate symptoms of gastro-oesophageal reflux unless asked, which presents difficulties where patients are followed up by practitioners unfamiliar with oesophageal stents. Operators may find it difficult to keep up with the rapid advance of stent designs, and the data suggest that removable and valved stents are being underused.

Pre-dilatation of strictures is occasionally required with larger delivery systems. This most commonly performed when string release Ultraflex systems were used. As there is an increased risk of perforation and haemorrhage dilatation should only be performed if the delivery system can not be advanced through the stricture.

Balloon dilatation immediately after stent placement was performed as often as pre-dilatation of the stricture. Stents continue to expand over several days after deployment and the temptation to treat the immediate radiographic appearance should be resisted. Nitinol stents in particular increase their radial force with warming to body temperature. Further intervention should be guided by the patient's symptomatic improvement. Occasionally the tip of the introducer system may impact in a poorly expanded stent on removal. This can usually be overcome by giving the stent some time to expand before further attempts at removal, but occasionally balloon dilatation is required to remove the delivery system [8]. Some delivery systems are available with an inflatable tip (Fer-X Ella) or allow release of the introducer tip (Fer-X Ella, Choo/Do) after deployment avoiding the risk of impaction.

Significant complications were rare and apparently more common with older and stiffer stent models. The overall complication rate with modern stents is 7-15%, which compares well with earlier devices [26, 30]. Stent induced chest pain, seen in over 20% of earlier stent designs occurs in around 5% of patients treated with a soft nitinol stent [31, 32, 33]. However, the requirement for re-intervention remains high and increases with time. The need for providing a reliable point of access for the patients in case of recurrent symptoms cannot be overemphasised.

The decision at which time to stent a patient with minimal dysphagia, can be a difficult one. The data raise the question whether earlier stenting is beneficial and in terms of nutrition that may well be the case. However trials assessing patients' nutritional status and its improvement or delayed decline after stenting are required.

Although oesophageal stenting is relatively easy to perform, considerable skill may be required in the management of complications [34]. This often requires endoscopy and a good communication within the multi-disciplinary team is vital.

Centres with a large stent workload are likely to have better results, but this needs to be set against the delays in treatment associated with referring patients to other hospitals. The 50%-survival-time of patients requiring oesophageal stents is in the region of 3 months and prompt stent insertion is required when the dysphagia becomes limiting.

Database form

The following shows the sheet used for data acquisition. The sheet was expanded once during data acquisition to incorporate newer stent models.

Participating centres sent their sheets in as paper hard copies; data collection is intended to be internet-based in the future.

The British Society of Interventional Radiology

Oesophageal Stent Registry (ROST)

version 1.0 page 1

This form is designed so that questions requiring a single response are identified with round radio-buttons next to the options, whereas questions where more than one response may be selected are identified by square tick-boxes next to the options

Patient ID		Date-of-procedure	DD/MM/YYYY
Patient surname		Consultant code	
Patient forename		Hospital code	
Date-of-birth	DD/MM/YYYY	Date-of-admission	DD/MM/YYYY
Gender	○ Male ○ Female	Date-of-discharge	DD/MM/YYYY

Ethnic origin

○ Caucasian ○ Oriental
○ Negroid ○ Other

Previous procedures

Number of stents placed in the previous year

○ None ○ 11-20 stents
○ 1-5 stents ○ >20 stents
○ 6-10 stents ○ Unknown

Number of stents placed in the previous five years

○ None ○ 11-20 stents
○ 1-5 stents ○ >20 stents
○ 6-10 stents ○ Unknown

Pre-procedure data

Site of obstruction

☐ Above T1 ☐ Lower third - cardia
☐ Upper third ☐ Stomach - duodenum
☐ Mid third

Length of stricture

○ 1.0-5.0 cm ○ >10.0 cm
○ 5.1-10.0 cm ○ Unknown

Aetiology

☐ Malignant: Squamous cell Ca ☐ Benign: Perforation
☐ Malignant: Adeno Ca ☐ Benign: Oesophageal rupture
☐ Malignant: Fistula ☐ Benign: Reflux disease
☐ Malignant: Perforation ☐ Unknown
☐ Malignant: External compression
☐ Malignant: Recurrence following surgery

Dysphagia score

○ Normal diet
○ Some solid food ○ Liquids only
○ Semi-solids ○ Complete dysphagia

Pre-stent treatment

○ None
☐ Surgery ☐ Dilatation
☐ Laser therapy ☐ Thermal ablation
☐ DXT ☐ Brachytherapy
☐ Chemotherapy ☐ Photodynamic treatment
☐ Stent ☐ Other

Sedation / analgesia

☐ Midazolam ☐ Other opioid
☐ Diazepam ☐ Lignocaine throat spray
☐ Other benzodiazepine ☐ Reversal agent
☐ Pethidine ☐ NSAID
☐ Fentanyl

Position of patient

○ Supine ○ Lateral
○ Prone ○ Prone / oblique or Supine / oblique

Form presentation by Dendrite Clinical Systems Limited

The British Society of Interventional Radiology
Oesophageal Stent Registry (ROST)

version 1.0 page 2

This form is designed so that questions requiring a single response are identified with round radio-buttons next to the options, whereas questions where more than one response may be selected are identified by square tick-boxes next to the options

Patient ID		Date-of-procedure: DD/MM/YYYY

Procedure data

Radiology nurse present during procedure	○ No ○ Yes ○ Radiographer ○ Ward nurse ○ Other observer
Anaesthetist present	○ No ○ Yes
Number of stents used	○ One ○ Two

Stent details

	Stent 1	Stent 2
Stent used	○ Covered Wallstent ○ Uncovered Wallstent ○ Flamingo Wallstent ○ Gianturco ○ DUA anti-reflux ○ Covered Ultraflex ○ Uncovered Ultraflex ○ Instent ○ Choo ○ Covered memotherm ○ Fer X Ella ○ DO stent ○ NIT-S ○ NIT-S double ○ DO anti-reflux ○ Fer-X Ella anti-reflux ○ Other	○ Covered Wallstent ○ Uncovered Wallstent ○ Flamingo Wallstent ○ Gianturco ○ DUA anti-reflux ○ Covered Ultraflex ○ Uncovered Ultraflex ○ Instent ○ Choo ○ Covered memotherm ○ Fer X Ella ○ DO stent ○ NIT-S ○ NIT-S double ○ DO anti-reflux ○ Fer-X Ella anti-reflux ○ Other
Stent batch number		
Stent serial number		
Length of stent	cm	cm
Minimum stent diameter	mm	mm
Maximum stent diameter	mm	mm
Technically successful stent placement	○ No ○ Yes	○ No ○ Yes
Pre-stent balloon or rigid dilatation	○ No ○ Yes	○ No ○ Yes
Balloon pre-stent diameter	mm	mm
Post-stent balloon dilatation	○ No ○ Yes	○ No ○ Yes
Balloon post-stent diameter	mm	mm

Endoscopic assistance	○ No ○ Yes
Suction available	○ No ○ Yes - used ○ Yes - not used
Monitoring	○ None ☐ Pulse oximetry ☐ Supplemental O_2 ☐ ECG ☐ Blood pressure ☐ Pulse

Form presentation by Dendrite Clinical Systems Limited

The British Society of Interventional Radiology
Oesophageal Stent Registry (ROST)
version 1.0 **page 3**

This form is designed so that questions requiring a single response are identified with round radio-buttons next to the options, whereas questions where more than one response may be selected are identified by square tick-boxes next to the options

Patient ID ____ Date-of-procedure DD/MM/YYYY

Outcomes

Immediate complications
- ○ None
- ☐ Chest pain
- ☐ Haemorrhage
- ☐ Perforation
- ☐ Aspiration
- ☐ Stent misplacement
- ☐ Reflux
- ☐ Death

Prophylactic anti-reflux medication
- ○ None
- ☐ Anti-acids
- ☐ H_2-blockers
- ☐ Protein pump inhibitors

Post-stent contrast swallow
- ○ No
- ○ Yes

Patient status at discharge
- ○ Alive
- ○ Died in Radiology Suite
- ○ Died in hospital

Date-of-in-hospital-death DD/MM/YYYY

Cause of death (if known)
- ○ Not applicable
- ☐ MI
- ☐ Pneumonia
- ☐ CVA
- ☐ Haematemesis
- ☐ Stent-related
- ☐ Not stent-related
- ☐ Other

Follow up

Follow-up period
- ○ 1 month
- ○ 2 months
- ○ 3 months
- ○ 6 months
- ○ >6 months

Dysphagia score
- ○ Normal diet
- ○ Some solid food
- ○ Semi-solids
- ○ Liquids only
- ○ Complete dysphagia

Late complications
- ○ None
- ☐ Stent migration
- ☐ Pain
- ☐ Reflux
- ☐ Stent perforation
- ☐ Haemorrhage
- ☐ Tumour overgrowth
- ☐ Tumour ingrowth
- ☐ Food impaction

Number of endoscopies post-stent placement
- ○ None
- ○ One
- ○ Two
- ○ Three
- ○ Four
- ○ More than four
- ○ Unknown

Further treatment post-stent
- ○ None
- ☐ Surgery
- ☐ Laser therapy
- ☐ DXT
- ☐ Dilatation
- ☐ Brachytherapy
- ☐ Other
- ☐ Chemotherapy

Further stent placement
- ○ No
- ○ Yes

Patient status at follow up
- ○ Alive
- ○ Late disease-related death
- ○ Late disease-unrelated death

Date-of-death DD/MM/YYYY

Cause of death (if known)
- ○ Not applicable
- ☐ MI
- ☐ Pneumonia
- ☐ CVA
- ☐ Underlying disease
- ☐ Haematemesis
- ☐ Other
- ☐ Unknown

Form presentation by Dendrite Clinical Systems Limited

Notes

Notes

Notes

Notes

References

[1] Keogh B and Kinsman R. Fifth National Adult Cardiac Surgical Database Report 2003; Improving outcomes for patients. London. Society of Cardiothoracic Surgeon of Great Britain and Ireland. 2004.

[2] Laasch HU, Martin DF, Do YS, Kocher M, Valette PJ. Interventional radiology for the management of inoperable carcinoma of the oesophagus. *Endoscopy* 2003; **35**: 1049-57, discussion 1058

[3] The Royal College of Radiologists. Safe Sedation, Analgesia and Anaesthesia within the Radiology Department. 2003 http://www.rcr.ac.uk/pubtop.asp?PublicationID=186

[4] Marriott P, Laasch HU, Wilbraham L, Marriott A, England RE, Martin DF. Conscious sedation for endoscopic and non-endoscopic interventional gastrointestinal procedures: meeting patients' expectations, missing the standard. *Clin Radiol* 2004; **59**: 180-5

[5] Bell JK, Laasch H-U, Wilbraham L, England RE, Morris JA, Martin DF. Bispectral Index Monitoring for Conscious Sedation in Intervention: Better, Safer, Faster. In press: *Clin Radiol*

[6] Kang SG, Song HY, Lim MK, Yoon HK, Goo DE, Sung KB. Esophageal rupture during balloon dilatation of strictures of benign or malignant causes: prevalence and clinical importance. *Radiology* 1998; **209**: 741-746

[7] Owen A, Laasch H-U, Marriott A, Wilbraham L, England RE, Martin DF. Oesophageal stent follow-up: Routine contrast swallow does not add to the management. (Abstract). *Cardio Vasc Intervent Radiol* 2003; **26** (2): 197

[8] Laasch HU, Marriott A, Wilbraham L, Tunnah S, England RE, Martin DF. Effectiveness of open versus antireflux stents for palliation of distal esophageal carcinoma and prevention of symptomatic gastroesophageal reflux. *Radiology* 2002; **225**: 359-65

[9] Kocher M, Dlouhy M, Neoral C, Buriankova E, Gryga A, Duda M, Aujesky R. Esophageal stent with antireflux valve for tumors involving the cardia: work in progress. *J Vasc Interv Radiol* 1998; **9**:1007-10

[10] Nunes CC, Waechter FL, Sampaio JA, Pinto RD, Alvares-Da-Silva MR, Pereira-Lima L. Comparative post-operative study of prostheses, with and without an anti-reflux valve system, in the palliative treatment of esophageal carcinoma. *Hepatogastroenterology* 1999; **46**: 2859-64

[11] Do YS, Choo SW, Suh SW, Kang WK, Rhee PL, Kim K, Shim YM, Park KB, Han YH, Choo IW. Malignant esophagogastric junction obstruction: palliative treatment with an antireflux valve stent. *J Vasc Interv Radiol* 2001; **12**(5): 647-651

[12] Dua KS, Kozarek R, Kim J, Evans J, Medda BK, Lang I, Hogan WJ, Shaker R. Self-expanding metal esophageal stent with anti-reflux mechanism. *Gastrointest Endosc* 2001; **53**(6): 603-613

[13] Ramirez FC, Dennert B, Zierer ST, Sanowski RA. Esophageal self-expandable metallic stents--indications, practice, techniques, and complications: results of a national survey. *Gastrointest Endosc* 1997; **45**: 360-4

[14] Medicines and Healthcare Products Regulatory Agency 2001; SN 2001 (10) - Flamingo Wallstent Oesophageal Stent - Change in Instructions for Use. http://www.medical-devices.gov.uk/mda/mdawebsitev2.nsf/0/ED16F943FDA14C2100256A9A005ACEFC?OPEN

[15] Mohammed MA, Cheng KK, Rouse A, Marshall, T. Bristol, Shipman, and clinical governance: Shewhart's forgotten lessons. *Lancet* 2001; **357**: 463-467

[16] Adab P, Rouse A, Mohammed MA, Marshall, T. Performance league tables: the NHS deserves better. *BMJ* 2002; **324**: 95-98

[17] Egger M, Davey Smith G, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. *BMJ* 1997; **315**: 629-634

[18] Stark J, Gallivan S, Lovegrove J, Hamilton JRL, Monro JL, Pollock JCS, Watterson KG. Mortality rates after surgery for congenital heart defects in children and surgeons' performance. *Lancet* 2000; **355**: 1004-1007

[19] De Palma GD, di Matteo E, Romano G, Fimmano A, Rondinone G, Catanzano C. Plastic prosthesis versus expandable metal stents for palliation of inoperable esophageal thoracic carcinoma: a controlled prospective study. *Gastrointest Endosc* 1996; **43**: 478-82

[20] Adam A, Ellul J, Watkinson AF, Tan BS, Morgan RA, Saunders MP, Mason RC. Palliation of inoperable esophageal carcinoma: a prospective randomized trial of laser therapy and stent placement. *Radiology* 1997; **202**: 344-8

[21] Lagergren J, Bergstrom R, Lindgren A, Nyren O. Symptomatic gastroesophageal reflux as a risk factor for esophageal adenocarcinoma. *N Engl J Med* 1999; **340**: 825-831

[22] Sihvo EI, Salminen JT, Ramo OJ, Salo JA. The epidemiology of oesophageal adenocarcinoma: has the cancer of gastric cardia an influence on the rising incidence of oesophageal adenocarcinoma? *Scand J Gastroenterol* 2000; **35**(10): 1082-1086

[23] Bollschweiler E, Wolfgarten E, Gutschow C, Holscher AH. Demographic variations in the rising incidence of esophageal adenocarcinoma in white males. *Cancer* 2001; **92**: 549-555

[24] Chan AC, Shin FG, Lam YH, Ng EK, Sung JJ, Lau JY, Chung SC. A comparison study on physical properties of self-expandable esophageal metal stents. *Gastrointest Endosc* 1999; **49**: 462-465

[25] Vakil N, Morris AI, Marcon N, Segalin A, Peracchia A, Bethge N, Zuccaro G, Bosco JJ, Jones WF. A prospective, randomized, controlled trial of covered expandable metal stents in the palliation of malignant esophageal obstruction at the gastroesophageal junction. *Am J Gastroenterol* 2001; **96**: 1791-1796

[26] Sabharwal T, Hamady MS, Chui S, Atkinson S, Mason R, Adam. A randomised prospective comparison of the Flamingo Wallstent and Ultraflex stent for palliation of dysphagia associated with lower third oesophageal carcinoma. *Gut* 2003 **52**: 922-6

[27] Song HY, Lee DH, Seo TS, Kim SB, Jung HY, Kim JH, Park SI. Retrievable covered nitinol stents: experiences in 108 patients with malignant esophageal strictures. *J Vasc Interv Radiol* 2002; **13**: 285-93

[28] Ho HS, Ong HS. A rare life-threatening complication of migrated nitinol self-expanding metallic stent (Ultraflex). *Surg Endosc* 2004 **18**: 347

[29] Song HY, Jung HY, Park SI, Kim SB, Lee DH, Kang SG, Il Min Y. Covered retrievable expandable nitinol stents in patients with benign esophageal strictures: initial experience. *Radiology* 2000; **217**: 551-7

[30] Siersema PD, Hop WC, van Blankenstein M, van Tilburg AJ, Bac DJ, Homs MY, Kuipers EJ. A comparison of 3 types of covered metal stents for the palliation of patients with dysphagia caused by esophagogastric carcinoma: a prospective, randomized study. *Gastrointest Endosc* 2001; **54**: 145-53

[31] Laasch HU, Nicholson DA, Kay CL, Attwood S, Bancewicz J. The clinical effectiveness of the Gianturco oesophageal stent in malignant oesophageal obstruction. *Clin Radiol* 1998; **53**: 666-72

[32] Golder M, Tekkis PP, Kennedy C, Lath S, Toye R, Steger AC. Chest pain following oesophageal stenting for malignant dysphagia. *Clin Radiol* 2001; **56**: 202-205

[33] Schmassmann A, Meyenberger C, Knuchel J, Binek J, Lammer F, Kleiner B, Hurlimann S, Inauen W, Hammer B, Scheurer U, Halter F. Self-expanding metal stents in malignant esophageal obstruction: a comparison between two stent types. *Am J Gastroenterol* 1997; **92**: 400-6

[34] McManus K, Khan I, McGuigan J. Self-Expanding oesophageal stents: strategies for re-intervention. *Endoscopy* 2001; **33**: 601-4

British Society of
Interventional
Radiology

Mrs Lavinia Gittins
BSIR Administrator
4 Verne Hill
Ampthill
Bedford
MK45 2PS

Phone: (+44) 01525 403 026
Fax: (+44) 01525 751 384
email: office@bsir.org

DENDRITE
CLINICAL SYSTEMS LTD

Dr Peter K H Walton
Managing Director
Dendrite Clinical Systems Ltd
59A Bell Street
Henley-on-Thames
Oxfordshire RG9 2BA

Phone: (+44) 01491 411 288
Fax: (+44) 01491 411 377
email: publishing@e-dendrite.com
www.e-dendrite.com