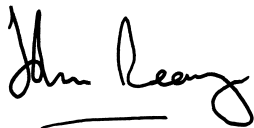


London Bridge Hospital

I am delighted to write an introduction to the London Bridge Hospital PTCA report. Audit data collection at this level represents a great deal more than dry figures. An enormous amount of teamwork and effort has gone into collecting data from busy and committed medical staff. The results compare very favourably with those of any centre NHS or private in the UK.

Thanks go in particular to Drs Michael Webb-Peploe and David Brennand Roper as well as Drs Cliff Bucknall and Kamal Ahmed for their input and guidance in reviewing the report. To ensure accuracy and timeliness, the data was derived from pre assessment by the cardiac nursing assessment team and then upon admission from the angiography nursing team. Our cardiac technicians collected procedural data during each operation which was verified by the physician in charge before the patient had left the treatment area. All of these clinical teams showed enthusiasm and a determination to get the data collected to the highest standard from the start. Finally, my thanks go in particular Lucia Katsumbe-Maclean our specialist nurse in charge of maintaining all our cardiac outcome databases (PTCA and surgical) and to her supporting team of medical students who take pride in the accuracy of their work.

Two final points of note: firstly, throughout the reporting period the drug eluting stent was available to all our patients. The private medical insurance companies have to be congratulated for identifying and responding quickly to ensure the benefits of these stents were made available to their customers. Secondly, the successful clinical and medical teamwork exhibited in this report forms the basis for London Bridge Hospital's ongoing initiative to become a recognized cardiac centre of excellence. The secret to this lies in multidisciplinary teamwork and cooperation to ensure best practice at every stage of treatment. This report represents very encouraging evidence of such teamwork.



John Reay
Chief Executive Officer
London Bridge Hospital

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INTRODUCTION

Percutaneous Coronary Intervention (PCI) is a recognised, growing mode of revascularisation for patients with coronary artery disease. The London Bridge Hospital has been contributing data to the British Interventional Cardiology Society (BCIS) National Audit project for a number of years. However, the data capture was largely paper based and recorded manually by London Bridge Cathlab staff.

In October 2002, we started using clinical audit software, the Patients Analysis & Tracking System. This system has been used successfully at the hospital for the capture of cardiac surgery data since 1998. The aim is to provide a more reliable and timely account of interventions and outcomes. Cardiologists at the centre are also expected to benefit in having access to both Unit data and their own patient data to add to their revalidation portfolios.

Audit Requirements:

According to BCIS there are three main requirements for the successful implementation of PCI audit. These requirements are as follows; ⁽¹⁾

1) The trust (in this case the company, HCA limited) should;

- Establish an audit process for coronary intervention
- Support cardiologists in establishing the infrastructure required
- Provide appropriate information technology and data personnel
- Ensure internal compliance with external review process

2) The Cardiac department should;

- Identify key people for audit process
- Provide time and space to allow audit process to work (including meetings)
- House necessary IT hardware
- Ensure accurate data collection
- Ensure compliance with CCAD and BCIS

3) BCIS / CCAD will;

- Provide accreditation for the data collection process
- Provide data sets and consistent definitions of variables
- Provide specification for compatibility with the BCIS/CCAD database
- Provide methodology for data verification, data analysis and feedback
- Provide professional support

The Change Process:

One of the main obstacles to accurate capture of procedural data is that clinical monitoring equipment cannot be used for audit and there is no direct interface between this equipment and the audit system.

Not all variables required for National Audit are or can be measured and documented during the procedure. Left ventricular ejection fraction for example, if not measured (where necessary before the procedure), by means of echocardiography will be eyeballed and estimated by the cardiologist. The extent of lesion stenosis is also often estimated.

Improving Data quality

The following solutions were adopted to improve the quality of the data entered onto the audit system:

- The ward admission assessment form, (completed by nursing staff) was improved to incorporate the BCIS variables. Definitions were provided where necessary for example CCS score and NYHA score.
- The assessment form was further improved to include medical examination findings and notes obtained by the Resident Medical Officers on admission.
- The Cathlab nursing documentation was improved to provide more detail on peri-procedure devices and complications.
- The Cathlab technicians started completing a form that would assist in the capture of audit data in relation to the procedure. The cardiologist would be consulted soon after the procedure for details on extent of lesion and LV ejection fraction. This form is still in use and has recently been updated to the latest BCIS dataset version 5.1.2

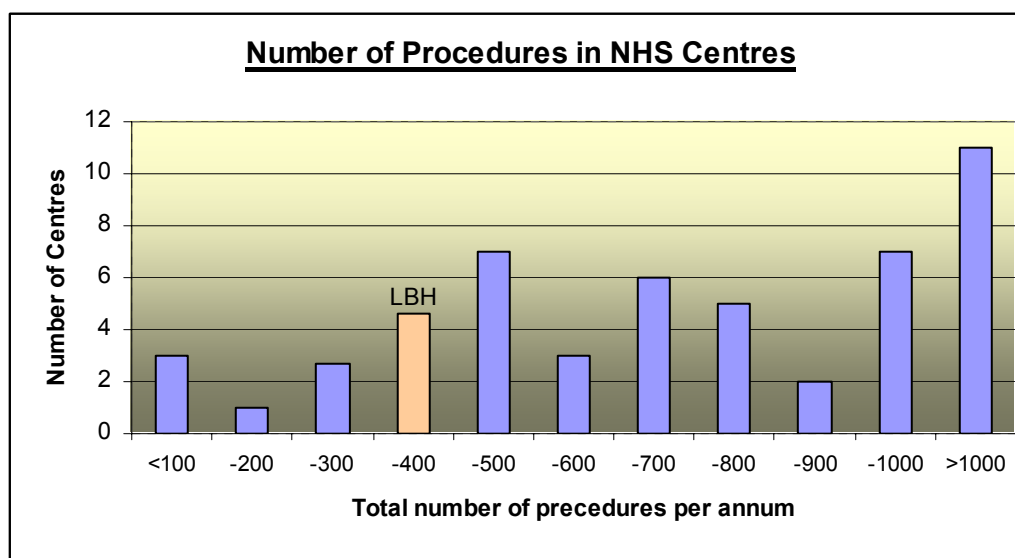
Note:

London Bridge Hospital has submitted data to BCIS in the past but the data submitted was paper based and incomplete. In June 2004 the London Bridge Hospital along with the Wellington Hospital and the Harley Street Clinic, submitted more comprehensive data which included procedure details as well as hospital outcomes.

National Service Frameworks targets:

According to a joint statement by BCIA (British Cardiovascular Industry Association) and NICE (National Institute of Clinical Excellence), ⁽²⁾ there is substantial under-provision of revascularisation services in the UK, resulting in increased waiting times. This presents a tremendous opportunity for the independent hospitals to help achieve the National Service Frameworks targets for Coronary Revascularisation which are as follows:

1. To increase to 750 pm PCIs, requires a 13% growth in PCI activity
2. To increase to 750 pm CABGs*, requires a 57% growth in CABG activity
3. To increase to 1500 pm revascularisations with 500 by CABG and 1000 by PCI, requires a 5% growth in CABG and a 51% growth in PCI



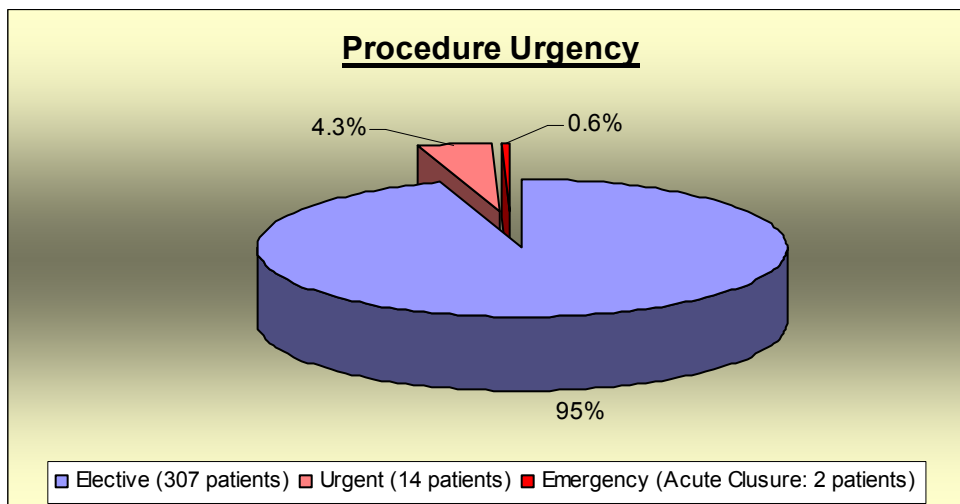
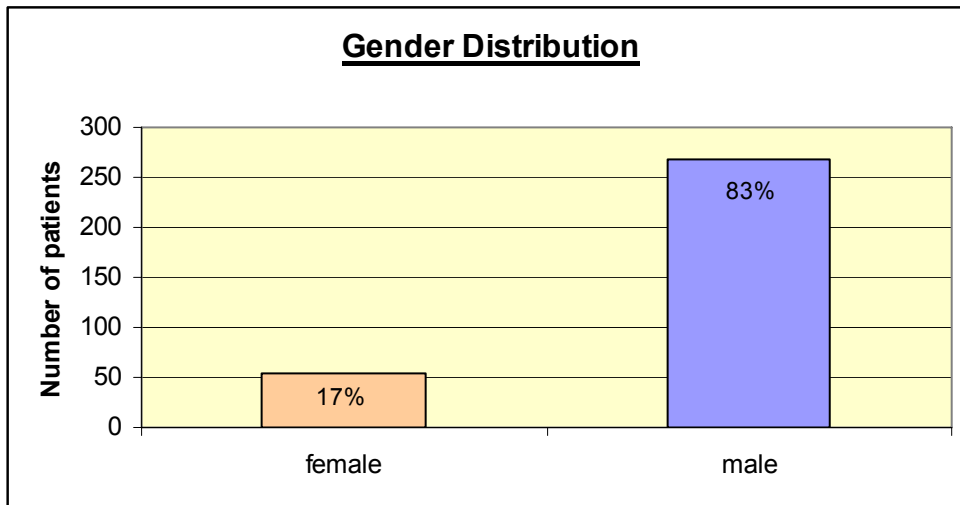
This report covers the full year period of January 2003 to December 2003. During this period the London Bridge hospital as a unit carried out 323 PCIs, performed by 20 different Consultant Interventionists.

Group Summary 2003: (Number of PCI procedures per month)

	Occurrences	Percentage
01 Jan 2003-31 Jan 2003	31	9.60%
01 Feb 2003-28 Feb 2003	28	8.70%
01 Mar 2003-31 Mar 2003	43	13.30%
01 Apr 2003-30 Apr 2003	24	7.40%
01 May 2003-31 May 2003	29	9%
01 Jun 2003-30 Jun 2003	22	6.80%
01 Jul 2003-31 Jul 2003	31	9.60%
01 Aug 2003-31 Aug 2003	15	4.60%
01 Sep 2003-30 Sep 2003	26	8%
01 Oct 2003-31 Oct 2003	27	8.40%
01 Nov 2003-30 Nov 2003	24	7.40%
01 Dec 2003-31 Dec 2003	23	7.10%

323 entries

Pre- Operative Information:



Other Pre- Operative variables

Previous CABG

	Occurrences	Percentage
No	259	80.20%
Yes	64	19.80%

323 entries

Previous PCI

	Occurrences	Percentage
No	240	74.30%
Yes	83	25.70%

323 entries

Diabetes Management

	Occurrences	Percentage
Not diabetic	263	81.40%
Diabetes (dietary control)	5	1.50%
Diabetes (oral medicine)	37	11.50%
Diabetes (insulin)	18	5.60%

323 entries

Previous MI

	Occurrences	Percentage
No	249	77.10%
Yes	74	22.90%

323 entries

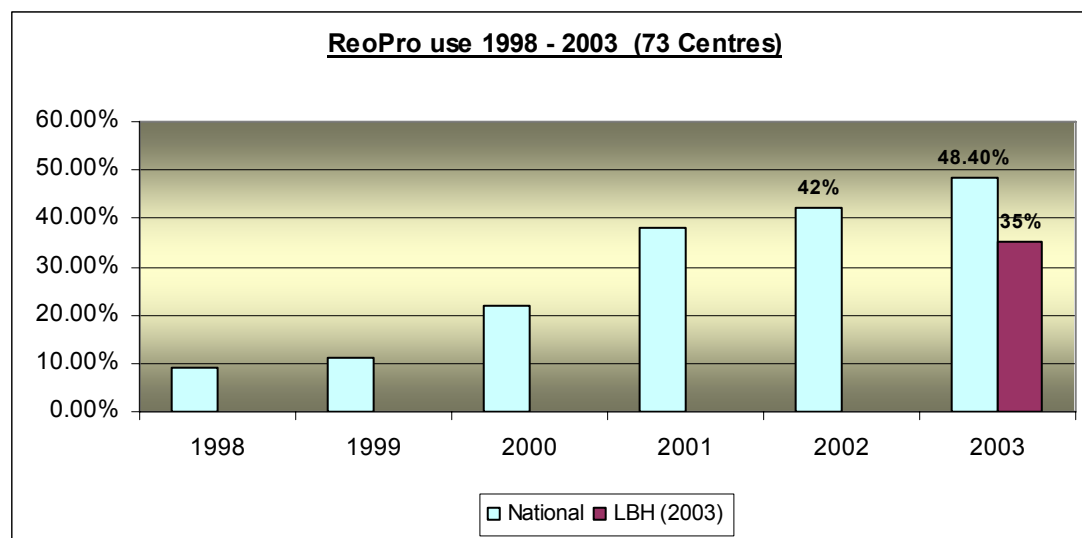
Acute Coronary Syndrome:

The definition of acute coronary syndromes (ACS) includes patients presenting with ischaemic cardiac chest pain of recent origin in the following categories:

- Unstable angina
- Non-Q-wave myocardial infarction
- Acute myocardial infarction (MI) with ST segment elevations and Q wave development

Patients who experience abrupt closure of a coronary artery during percutaneous coronary intervention (PCI) represent an additional category of ACS.

Use of ReoPro



The lower usage of Reopro at the London Bridge Hospital may be a reflection of the number of stable versus unstable patients. The National Institute for Clinical Excellence, on the 9th December 2003, issued the following guidance recommending the use of I Ib/IIIa blockers.

"Glycoprotein I Ib/IIIa Inhibitors should be given to high risk patients who have either a minor heart attack, unstable angina or who are undergoing a balloon angioplasty." ⁽³⁾
<http://www.nice.org.uk>

GPIIb/IIIa inhibitors can prevent platelet aggregation when PCI with (or without) stents is undertaken. Intravenous GP I Ib/IIIa inhibitors are administered by initial (bolus) dose, followed by a constant infusion over 12 to 96 hours depending on the half-life of the drug to maintain platelet blockade during the period of vessel healing. Most GP I Ib/IIIa inhibitors act for only short time periods, so require infusion times of from two to four days. Abciximab (ReoPro) acts for a much longer time, and is therefore infused for only 12 hours.

Use of Clopidogrel

According to a recent article published by Heartwire.org (2003), for stable patients undergoing routine, uncomplicated angioplasty and stenting, many cardiologists are switching to a 600-mg loading dose of clopidogrel pre-PCI, as this dose achieves maximal inhibition of platelets in just two hours. "Many believe clopidogrel also reduces the need for I Ib/IIIa blockers". ⁽⁴⁾

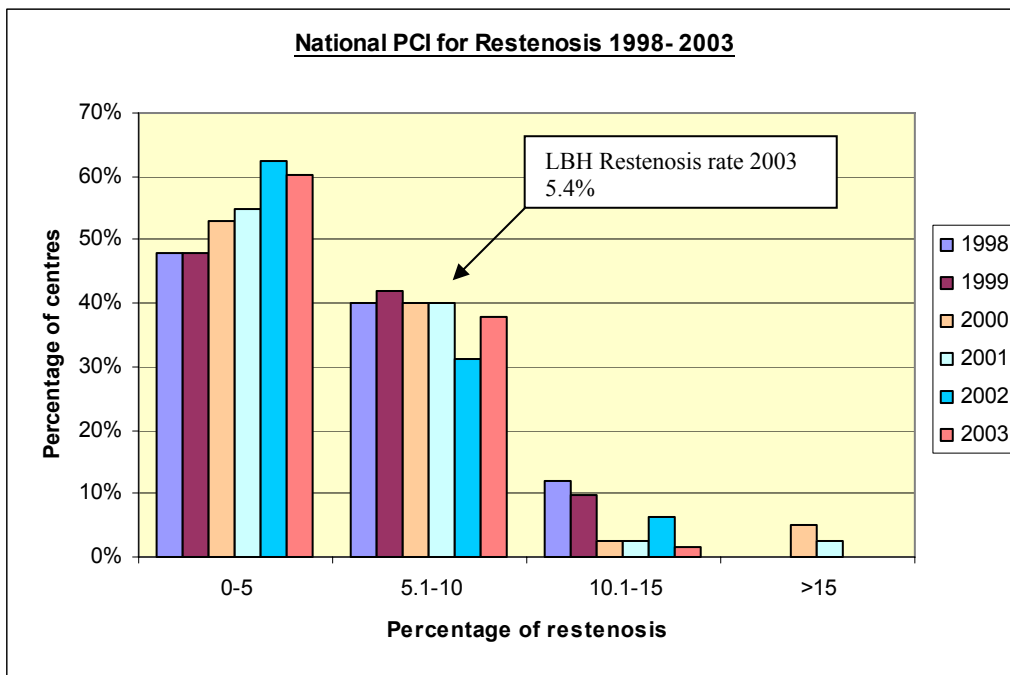
Restenosis

The weakness of PCI is that a proportion of patients suffer recurrence of symptoms due to renarrowing (restenosis) of the treated segment requiring a repeat procedure, usually within 12 months of the original treatment. ⁽⁵⁾

Patients with small diameter arteries, longer segments of disease, disease of more than one artery, multiple stent implantation and diabetes are at increased risk of restenosis.

National trends for restenosis following PCI

	'92	'93	'94	'95	'96	'97	'98	'99	'00	'01	02	lbh '03
% stenting	2.7	5.6	13.5	27.6	45.9	60	69	79	84	86	86.4	96.4
% Restenosis	11.6	12.3	11.4	9.6	9.4	7.4	5.2	5.7	6.2	5.4	4.7	5.4



The rate of stenting for restenosis has seen a steady decline over the years as shown above. Nationally in 2002, over 60% of centres had a restenosis rate of 0 to 5%. Only 5% of centres in 2002 showed poorer performance of up to 15% restenosis. In 1998, about 47% of centres achieved 0 to 5% restenosis. 12% of centres in 1998 had restenosis rate of up to 15%. In the last two years, this success has been attributed to the introduction of drug eluting stents⁽⁵⁾

Use of stents in PCI

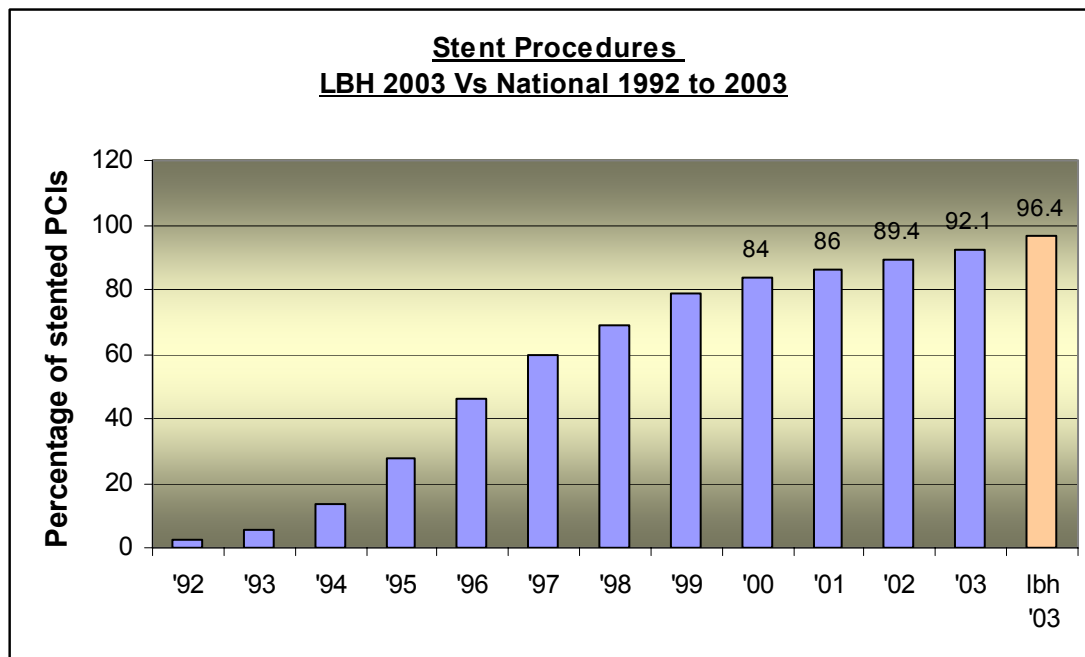
312 Patients out of the 323 cases had stents inserted. There were 282 single vessels attempted, 38 double vessels and 3 triple vessels as shown below.

Number of vessels attempted per patient

	Number	Percentage
One	282	87.30%
Two	38	11.80%
Three	3	0.90%

323

Entries



Number of stents used per lesion

	Number	Percentage
None	15	3.6%
One	275	65.6%
Two	93	22.2%
Three	27	6.4%
Four	7	1.7%
Five	2	0.5%

419

attempted vessels

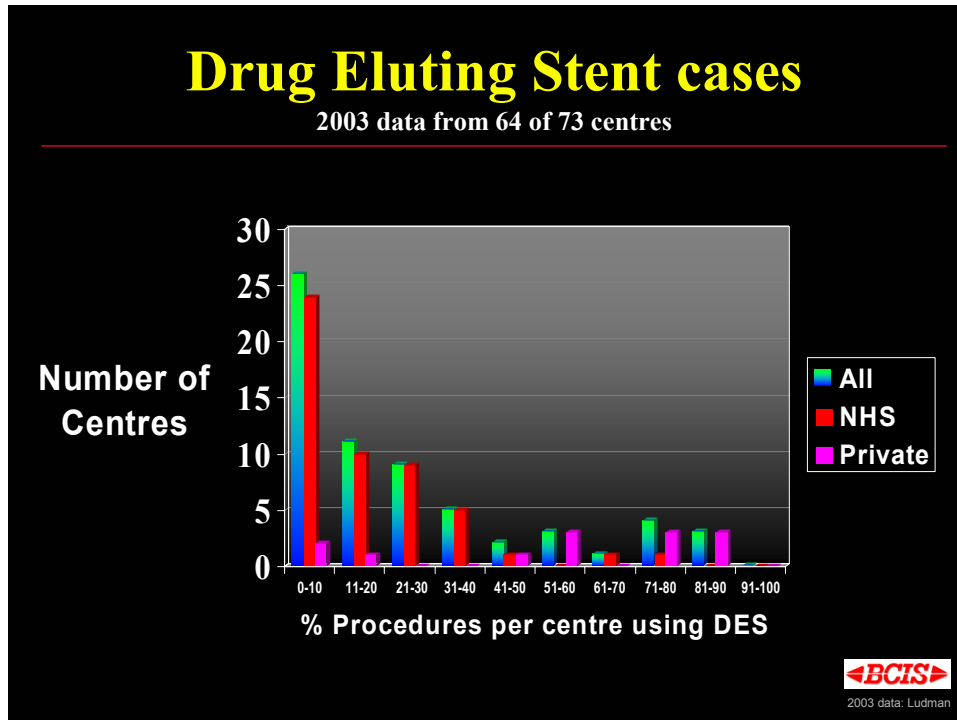
323

entries

Some of the vessels had more than one lesion. Altogether there were 405 lesions attempted. In most procedures (275 cases) only one stent was deployed per lesion. However some lesions required more two or more stents as shown above. 3.6% of lesions were not stented. 393 lesions were stented

Use of Drug Eluting Stents:

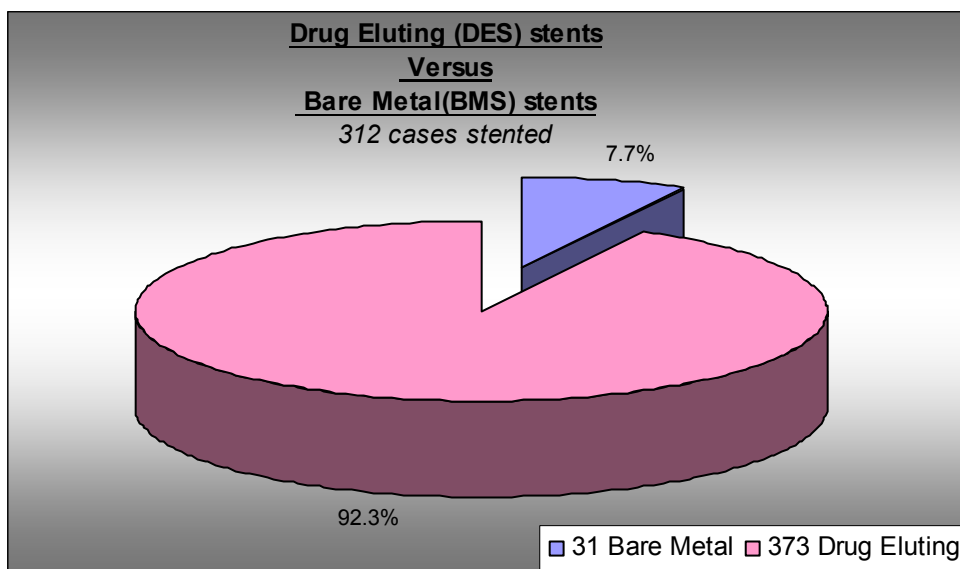
The steady decline in the number of patients requiring repeat revascularisation following PCI has been attributed to the use of drug eluting stents.



The BCIS report 2003 shows that the usage of drug eluting stents as recommended by NICE is more prevalent in the Private sector than it is in the NHS. The majority of NHS centres in 2003 only used drug eluting stents in up to 40% of cases.

The graph below shows the use of stents at the London Bridge Hospital:

96.4% of all attempted lesions were stented i.e. 312 patients.
288 patients had drug eluting stents inserted.



The most commonly used drug eluting stents are tabled below:

[Drug Eluting Stents at LBH:](#)

Paclitaxel (Taxus)	266	71.30%
Rapamycin (Cypher)	104	27.90%
Dexamethasone (Dexamet)	14	3.80%
	373	Attempted lesions
	288	entries

[NICE Guidelines / Recommendations:](#) ⁽⁶⁾

1. Stents should be used routinely where PCI is the clinically appropriate procedure for patients with either stable or unstable angina.
2. The decision to implant either a BMS or a DES should be based on target vessel anatomy, clinical symptoms and mode of presentation.
3. The use of a Cypher or Taxus stent is recommended for symptomatic patients with a target vessel internal diameter of *less than* 3mm or a lesion length *greater than* 15mm.
4. Patients for whom both PCI or CABG are appropriate techniques would, other things being equal, choose PCI in almost all cases, even though the chances of restenosis are greater.

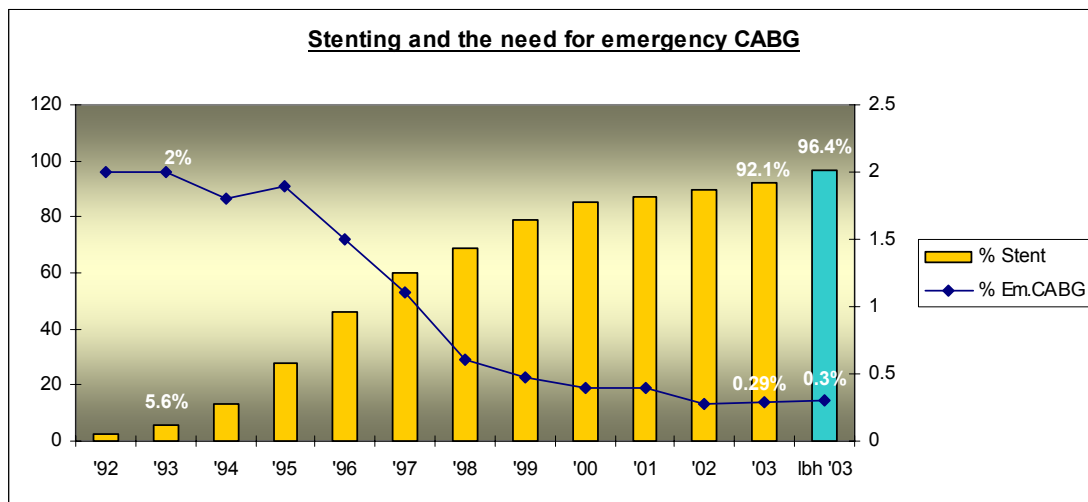
OUTCOMES

Emergency CABG

The graph below shows that in 1993 there were more emergency CABG cases relative to the percentage of stents inserted.

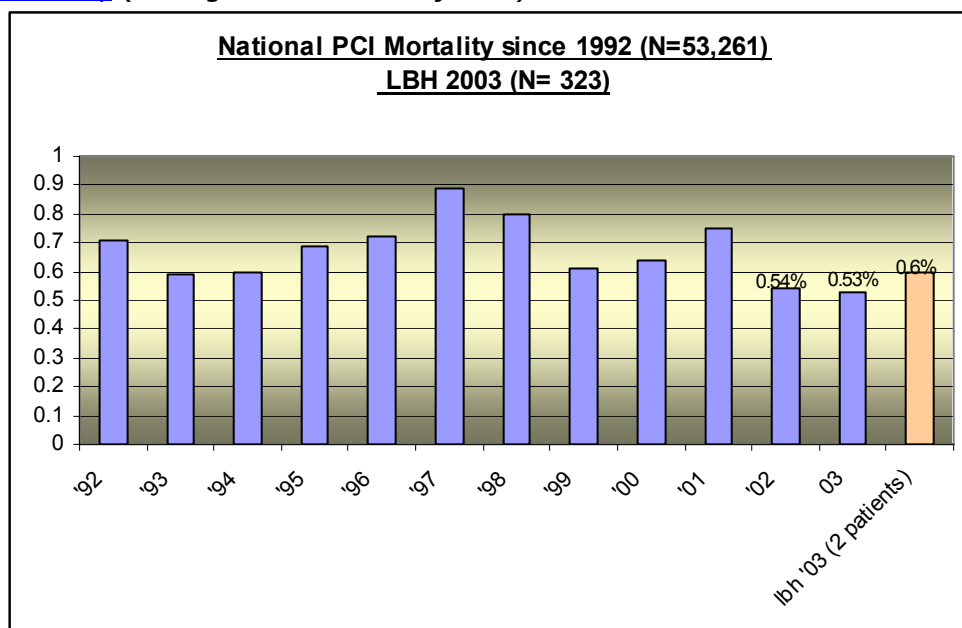
The London Bridge hospital figures for 2003 show that 96.4% of PCI interventions were stented and only 0.3% (2 patients), went on to have emergency CABG.

	'93	'94	'95	'96	'97	'98	'99	'00	'01	'02	'03	03 LBH
% Stent	5.6	13.5	27.6	45.9	60	69	79	85	87	84	92.1	96.4
% Em.CABG	2	1.8	1.9	1.5	1.1	0.6	0.48	0.4	0.4	0.28	0.29	0.3

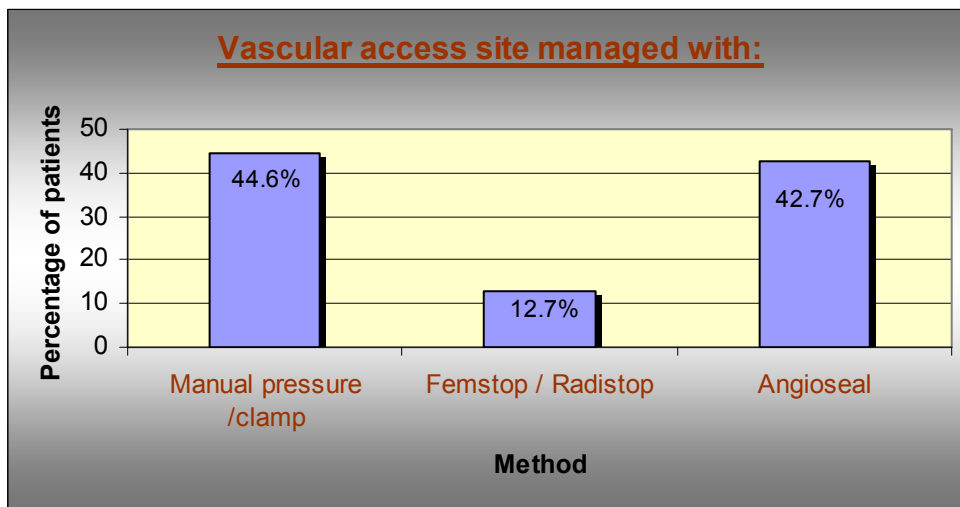


In 1993, the National figures show that 5.6% of PCI patients had stents inserted, 2% of them failed and went on to have emergency CABG. By the end of 2003, 92.1% of PCI had stents and only 0.29% of them went on to have emergency CABG. (7)

Mortality (raw figures: Not risk adjusted)



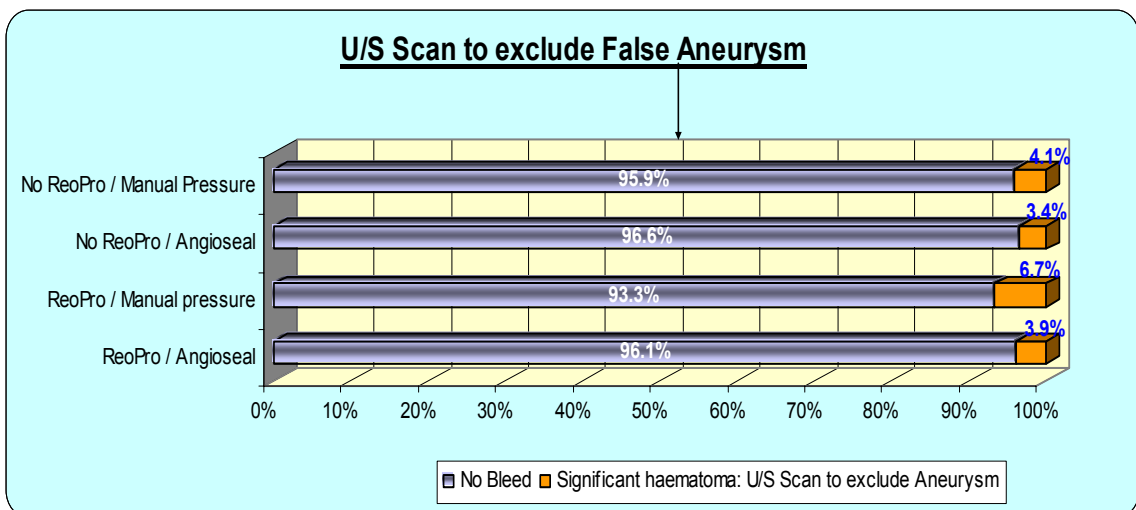
Management of Vascular Access Site:



A recent study (July 2003) Schroeder et al,⁽⁸⁾ concluded that failed haemostasis by artery closure devices in patients undergoing PCI who are treated with GP IIb/IIIa inhibitors is associated with significant vascular complications. AngioSeal may be associated with a higher failure rate, while manual compression and Perclose seem to be more effective with a lower complication rate.

The graph below shows the incidence at the London Bridge hospital (in percentage) of significant haematoma necessitating the use of ultra sound to exclude the diagnosis of "false aneurysm"

Vascular Site Bleeding: Complications Following PCI



Only 1 patient in the whole group of 323 patients had a positive false aneurysm diagnosed. This was a 69 years old female who had Reopro and an angioseal inserted post PCI.

Of the 111 patients in the LBH group who had ReoPro post PCI, 45.9% had an angioseal device inserted. 3.9% of these patients went on to develop a significant haematoma requiring ultra sound investigation to exclude false aneurysm.

Other Outcome Variables

Complication rates and long term outcomes for FOUR groups

CABG + PCI performed previously	7.73%	25 patients
CABG only performed previously	12.07%	39 patients
PCI only performed previously	17.96%	58 patients
First time PCI	62.22%	201 patients

Length of Stay (in Hours)

	Prev CABG & Prev PCI	PREV cabg only	Previous PCI ONLY	FIRST TIME PCI
Sample Size	25	39	58	201
Minimum Answer	18.08	19.23	8.92	0
Maximum Answer	90.13	112.38	6235.08	503
Mean	29.56	34.1	171.39	32.56
Median	23.03	24.43	24.71	23.8

Median: the value above and below which 50% of the individual values lie.

Restenosis:

		<u>Stenosis in previous grafts</u>	<u>Stenosis in previous stents</u>
CABG + PTCA performed previously	25	22 out of 30 attempted vessels	6 patient out of 30 attempted vessels
CABG only performed previously	39	33 out of 53 attempted vessels	
PTCA only performed previously	58		15 out of 72 attempted vessels

OBSERVED OUTCOMES FOR PATIENTS WITH PREVIOUS CABG

	Number	Success	Repeat PCI	CABG	MI	Death
National (inc native & grafts)	1556	81.20%	0.06%	0.26%	0.13%	0.30%
<u>LBH (inc native & grafts)</u>	64	95.3%	9.3%	4.7%	1.6%	1.6%
		61 patients	6 patients	3 patients	1 patient	1 patient
<u>LBH (grafts only stented)</u>	48	95.8%	14.6%	2.1%	2.1%	2.1%
		46 patients	7 patients	1 patient	1 patient	1 patient

Cardiac Enzymes Post OP

	Prev CABG & Prev PCI	PREV cabg only	Pre PCI ONLY	FIRST TIME PCI
Not Elevated < x2 ULN	100% or 24 patients	89.70% or 35 patients	86.20% or 50 patients	92% or 185 patients
Moderate elevation >x2 and <x5 ULN	0%	7.70% or 3 patients	12.10% or 7 patients	3.5% or 7 patients
Major elevation > or equal to x5 ULN	0%	2.60% or 1 patient	1.70% or 1 patient	4.5% or 9 patients

On this sample from the database, it appears that patients who have had previous coronary revascularisation have a lower incidence of sustaining a "major" elevation in cardiac enzymes than first time PCI patients. On the other hand the incidence of moderation seems greater overall for previous PCI and CABG patients.

Other PCI hospital Outcomes

	Prev CABG & Prev PCI	Prev CABG only	Prev PCI only	Fist Time PCI	
No PCI Complications	297	24	36	54	183
Q wave MI (stable & STEMI ONLY)	2	0	0	0	1
Non Q wave MI (stable only)	6	0	1	1	5
Elective CABG	8	1	2	1	4
Emergency CABG	1	0	0	0	1
Arterial complications	8	1	0	2	5
Death	2	0	1	0	1
Re-intervention PCI	2	0	0	0	2
Tamponade	1	0	0	0	1
VF Arrest	2	0	1		1
	<u>323</u>	<u>25</u>	<u>39</u>	<u>58</u>	<u>201</u>

Summary

PCI is less invasive than CABG, requires a shorter hospital stay, is a lower cost procedure and is generally preferred by patients.

1. The London Bridge figures for 2003 show good compliance with recommendations from the National Institute for clinical effectiveness for the use of ReoPro.
2. The lower usage of Reopro reflects a relatively smaller percentage of unstable patients treated at LBH compared to NHS (National figures).
3. According to the British Cardiovascular Industry Association, the introduction of drug-eluting stents is of clinical benefit to patients. The London Bridge hospital figures show good compliance with this recommendation.
4. The need for repeat revascularisation following restenosis consumes NHS resource. The London Bridge hospital rates for 2003, at 5.4% compare favourably with the latest available BCIS National rates.

References:

*NB - The National figures used in this report are taken from the BCIS National Report, produced and published on the BCIS website⁽¹⁾ by Dr. Peter F Ludman, National Audit Officer (Brighton 2003 and York 2004)

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