Bed-rest post-femoral arterial sheath removal – What is safe practice? A clinical audit

Jenny Tagney and Dawna Lackie

ABSTRACT

Numbers of patients undergoing coronary angiography and angioplasty procedures have increased in England due to targets within the National Service Framework for Coronary Heart Disease. Little evidence is available regarding optimal bed-rest duration for patients post-femoral arterial sheath removal following these procedures. Through literature review and clinical benchmarking, we aimed to identify what best practice was in the UK and whether bed rest times at our centre could be reduced without increasing complications to enable increased day case procedures. An audit tool was designed to collect data regarding method of obtaining haemostasis, length of bed-rest post-sheath removal and any post-procedural complications experienced by the patient. From a convenience sample of consecutive patients, 195 complete sets of baseline data revealed an average (median) period of 6-h bed rest. This was reduced to 3h and audit repeated yielding 176 complete data sets using the same audit tool. Femoral wound site complication rates were not significantly affected by reducing bed-rest time for diagnostic or interventional procedures. These findings contributed to an important change in practice, reducing length of stay post-procedure and should be re-explored due to increased use of femoral arterial closure devices.

Key words: Clinical audit • Angiography • Bed rest • Femoral arterial sheath removal

INTRODUCTION

By international standards, it was found that the United Kingdom (UK) has high rates of coronary heart disease (CHD), but low rates of coronary revascularization and people wait considerably longer in England for investigation and treatment (Department of Health, 2000), although this is reported to be improving (Department of Health, 2004). The National Service Framework (NSF) for CHD (Department of Health, 2000) set challenging target times from decision to investigate by a cardiologist to angiography. This should be no more than 3 months by April 2005 and the same time frame applies for revascularization procedures. Work to identify how and where existing services can accommodate additional patients continues through initiatives such as patient choice (Harrison-Boyle, 2003) and the CHD Collaborative as part of the NHS Modernization Agency. There has also been considerable investment in developing new or expanding existing cardiac centres throughout England (Department of Health, 2004). In contrast, clinical nursing practice in relation to pre and post-procedure care does not seem to have benefited from such investment or scrutiny. This is curious in the current climate where there is a growing call for evidence-based health care (Department of Health, 1996; Le May, 1999) and evidence-based nursing (Clarke, 2001; McClarey and Duff, 1997). Nurses' roles in relation to other areas of the NSF such as achieving optimal target times for thrombolysis in acute myocardial infarction, initiating, developing and co-ordinating cardiac rehabilitation programmes and developing enhanced follow-up services for patients with heart failure are well established and evidence-based (Thompson and Stewart, 2002). Yet the nurse's role in establishing standards of care for patients before, during and immediately post-angiography and angioplasty procedures has not been explored. However, this is an area receiving increasing attention due to the concept of 'generic workers' currently being explored by Skills for Health (on behalf of the Department Of Health) through the development of acute care

Author: Jenny Tagney, RGN, MSc Health Sciences (Clinical Practice), BSc (Hons) Nursing, ENB Coronary Care Nursing, Nurse Fellow of the European Society of Cardiology (NFESC), Cardiology Nurse Consultant, Bristol Royal Infirmary, United Bristol Healthcare Trust, Bristol, UK; Dawna Lackie, RGN, BSc (Hons) Nursing, ENB Interventional Nursing, Diagnostic Sales Representative, Cordis UK Ltd

Address for correspondence: Jenny Tagney, Cardiology Nurse Consultant, Level Three, Camden House, Bristol Royal Infirmary, United Bristol Healthcare Trust, Bristol BS2 8HW, UK

E-mail: jenny.tagney@ubht.swest.nhs.uk

competencies required to undertake various roles within the catheter laboratory (cath lab) environment (Skills for Health, 2004). With the proposed introduction of primary angioplasty to treat patients suffering myocardial infarction rather than the current thrombolytic treatments (Boyle, 2004), nursing workloads are likely to increase still further, so it is timely to explore care practices and roles that efficiently contribute to safe, effective procedures and recovery. Identifying the optimum length of bed-rest time required post-femoral arterial sheath removal to enable safe mobilization after angiography or angioplasty formed the basis of our enquiry so that we could ensure that our current practices were based on best possible evidence. Within '*A first class service*' (Department of Health, 1998), clinical governance is defined as a framework through which NHS organizations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish (Department of Health, 1998). Clinical audit is one way of contributing to these improvements in care.

REVIEWING THE EVIDENCE-BASE

The principles of clinical audit explore what is happening, what should be happening and what changes are needed (Cooper and Benjamin, 2004). At the inception of our enquiry in 1999, evidence to underpin the local policy of 6-h bed rest post-femoral arterial sheath removal appeared to be largely anecdotal and based on perceived potential for complications such as bleeding or haematoma if patients were mobilized sooner. To establish whether any standards for practice existed, we conducted a literature search using CINAHL and MEDLINE databases, inserting the terms angiography, percutaneous transluminal coronary angioplasty (PTCA, now more commonly referred to as PCI – percutaneous coronary intervention), femoral arterial sheath removal and bed rest for the period 1990–1999 (the year we commenced the enquiry). Of the 11 relevant studies retrieved, four related to reducing bed rest from 8 or 12 to 6h (Lau *et al*., 1993; Keeling *et al*., 1994; Price and Fowlow, 1994; Fowlow *et al*., 1995) and were therefore excluded from our review as this timeframe was consistent with our normal bed-rest time at the point of primary audit. All (bar one study, Lim *et al*., 1997) were conducted outside the UK. The search was repeated at the end of the audit revealing four other studies, two UK based, one from Hong Kong and two from North America (Burger *et al*., 1999; Keeling *et al*., 2000; Lee *et al*., 2000; Pollard *et al*., 2003; Roebuck *et al*., 2000), which are included in this review. An additional study was excluded as it concerned mobilization following femoral venous sheath removal (Gianakos *et al*., 2004 – TIBS IV)

Previous research has approached reducing bed-rest duration post-arterial sheath removal using a variety of patient groups and equipment. Kern *et al*. (1990) reduced the bed-rest time required by decreasing the arterial sheath size used during cardiac catheterization in 261 patients. Routine practice in their centre at that time involved using size 6- or 7-French femoral sheath, and reducing the average length of bed rest below 8h was viewed as a practical concern for most cardiologists. The average time was reduced to 2·6h (range 1·8–3·1h) with no significant increase in complications. Similarly, Steffenino *et al*. (1996) safely reduced bed rest from 6 to 3h post-cardiac catheterization using 5-French femoral sheaths with 191 patients. Koch *et al*. (1999) studied 300 patients following elective PTCA via 6-French femoral sheaths to evaluate the feasibility and safety of reducing bed rest from 4- to 2-h post-sheath removal having used low-dose heparin with no increase in complication rates.

Keeling *et al*. (1996) in TIBS II randomly assigned 86 patients following cardiac catheterization to receive 6- or 4-h bed rest post-femoral arterial sheath removal (they fail to mention sheath size). The study concluded no significant difference in the incidence of bleeding. Following on, TIBS III (Keeling *et al*., 2000) examined 51 patients undergoing PTCA to see whether their bed-rest times could also be reduced from 6 to 4h. They report that 98% (number not given) of patients had no adverse bleeding events following sheath removal. In response to these results, practice changed prior to completion of the study so that patients had 4h of bed rest routinely.

In the three UK-based studies, Lim *et al*. (1997) randomly assigned 200 consecutive angiography patients to either 4 or 6h of bed rest using 6-French sheath size, no anticoagulation and pneumatic compression device to achieve haemostasis, while Roebuck *et al*. (2000) allocated 117 angiography patients to 4h bed rest and 188 to 2h (anticoagulation not mentioned). Pollard *et al*. (2003) present results for 705 patients attending for planned, elective angiography (using 6-French sheaths), randomly allocated to either 4·5 (4-h flat, sit up for 30min) or 2·5h (1h flat, sit up for 1.5h) of bed rest. Exclusion criteria included any bleeding disorders or current anticoagulation therapy plus previous surgery to femoral arteries. This appears to be the most extensive study to date. None of the three studies reported increased complication rates in the reduced best-rest group and local policy changed to adopt the reduced period of bed rest as usual care. Interestingly, Lim *et al*. (1997) concluded that meticulous nursing by

motivated cardiac staff who were accustomed to groin care and rapid turnover contributed to the ability to shorten bed rest without compromising patient comfort, convenience and safety.

BENCHMARKING

Due to the paucity of literature available against which to measure our own effectiveness, a clinical benchmarking exercise was conducted to support the development of best clinical practice (Ellis *et al*., 2000). Eight other cardiac centres within the UK were contacted regarding their standard practice post-femoral arterial sheath removal to ascertain whether generic national standards existed but had not been published (Table 1).

It was apparent from the results of this exercise that there was no 'gold standard' to work towards and, indeed, considerable variation existed between centres nationally. It was therefore agreed to undertake a baseline audit of our own practice to establish complication rates for both diagnostic and interventional procedures with our current standard bed-rest time of 6h post-femoral arterial sheath removal. Bed rest would then be reduced in line with other reported studies and complication rates re-audited.

METHOD

Only patients who received their pre and post-procedure care within one regional cardiac centre were included. There were no other exclusion criteria as the purpose of the audit was to identify all-case complication rates before and after a reduction in bed-rest duration. The baseline study commenced in May 1999, and the follow-up audit data collection was completed in August 2000.

Using a convenience sample of consecutive patients, a total number of 200 baseline data sets (195 complete) were obtained using a specifically designed audit tool (see Appendix 1). Anticoagulation status and sheath size were noted, method and time devoted to achieving haemostasis documented, incidence of femoral wound site complications such as bleeding and haematoma were monitored plus other related complications such as vasovagal episodes. The audit was repeated following a reduction in bed rest to 3h, and a further 200 data sets were collected (176 complete) using the same tool to identify complications.

ETHICAL CONSIDERATIONS

Although clinical audit is not subject to formal ethical approval, ethical principles such as beneficence, justice, maintaining patient anonymity and confidentiality and non-malificence (Fletcher *et al*., 1995; ICN, 1996) must be adhered to. The optimum duration required for bed rest after removal of femoral sheaths was not clear, and other UK centres' practice varied from 2 to 12h, so even after reducing the duration to 3h, practice would remain above the minimum published bed-rest period. Monitoring any change in complication rates was intended to ensure that we 'did no harm' (non-malificence) by reducing the length of bed rest. Justice was achieved through the homogenous, convenience samples included for both 6 and 3h groups. All data collected were anonymized, clinical staff involved in caring for the patients were fully informed as to the purpose, and other care practices were not affected by conducting the audit. All data were stored as secure electronic files by the clinical audit facilitator according to Caldicott requirements to ensure confidentiality was maintained.

RESULTS

Of the total number of patients involved in both samples (n=372), 358 (96·2%) cases used 6-French sheaths and only 120 (32·3%) used an arterial closure device, all others used manual (digital) arterial compression (mean compression time 10min) to achieve haemostasis. As previously suggested, the baseline median time

Table 1 Benchmarking against other UK centres (NB at time of study commencement 1999)

Hospital	Bed-rest times (diagnostic) (h)	Bed-rest times (intervention) (h)	Sheath size (diagnostic)	Sheath size (intervention)	Achieving haemostasis
Heath, Cardiff	6	12	6 French	7 French	Manual
John Radcliffe, Oxford	4	4	6 French	8 French	Manual/compression clamp
Queen Elizabeth, Birmingham	2	4	6 French	6/8 French	Manual
Western General, Edinburgh	1	2	6 French	7/8 French	Manual
Freeman, Newcastle	4	6	5/6/7 French	6/7 French	Manual
Royal Brompton	4	6	5 French	7 French	Manual/angioseal
Royal Infirmary, Edinburgh	4	6	6 French	6 French	Manual
Glenfield, Leicester	2	4	4/5/6 French	7 French	Manual
Bristol Royal Infirmary	6	8	6 French	6/8 French	Manual/angioseal

of bed-rest post-sheath removal was 6h, which consisted of 2h lying flat (head supported by 1–2 pillows only) and 4h sitting at approximately 45° in bed. In the 3-h group, 1h was spent lying flat and 2h sitting at 45°. Similar ratios of diagnostic/interventional cases were documented in the 6 and 3h samples, with a slightly increased female:male ratio noted in the 3-h sample (Table 2).

Number of oozing or bleeding incidents increased from five (2·6%) in the 6-h group to 11 (6·3%) in the 3-h group, which was not statistically significant (χ^2 reveals p=0·333) (see Figure 1). In monitoring the anticoagulation status of subjects, it was noted that the number of patients receiving Glyco Protein IIb IIIa inhibitors had also increased, as had the use of an arterial closure device in the second audit (see Figure 2). However, when reviewing any links between GPIIb IIIa inhibitors and increased bleeding, again there was no statistical significance (Fischer's exact test reveals p=0·134).

Numbers of haematomas reduced from 29 in the 6-h group (14·8%) to 19 in the 3-h group (10·8%). Vaso-vagal episodes appeared to be associated only with patients who had endured prolonged periods of bed rest (e.g. patients had sheaths removed following 12h bed rest and were then allowed up after further 3h in bed).

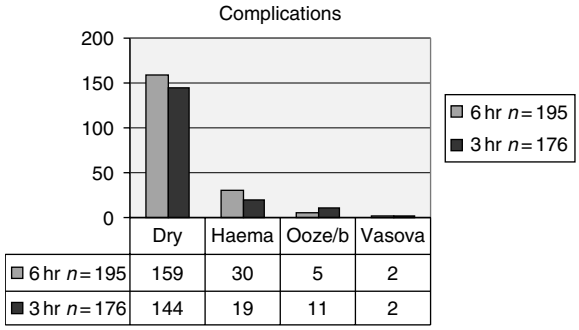
DISCUSSION

This audit has contributed to a significant change in clinical practice through ensuring our care complies with up-to-date evidence. Numbers in both 6- and 3-h groups are larger than several previous studies conducted outside the UK, which serves to enhance the validity of our results.

As previously stated, this is an important piece of work as there only appears to have been three other UK studies published relating to safe bed-rest times post-femoral arterial sheath removal (Lim *et al*., 1997; Roebuck *et al*., 2000; Pollard *et al*., 2003), all of which only examined complication rates in angiography patients. This audit incorporated both angiography and angioplasty patients, the latter often being viewed as being at greater risk of bleeding complications due to additional anticoagulopathy during the intervention (Koch, 1999). Although O'Grady (2002) describes the process of removing an arterial sheath following

Table 2 Gender and diagnostic/intervention mix

	6-h group (n=195) (%)	3-h group (n=176) (%)
Males	60·2 (118)	69·9 (123)
Females	39·8 (78)	30·1 (53)
Diagnostic	77 (151)	75·6 (133)
Intervention	23 (45)	24·4 (43)



	Dry	Haema	Ooze/b	Vasova
6 hr n=195	159	30	5	2
3 hr n=176	144	19	11	2

Figure 1 Anticoagulation and closure device use

PTCA, she fails to review the evidence for length of bed rest following this, basing local practice on one study (Keeling *et al*., 2000). Two previous UK studies were examining the effectiveness of a pneumatic arterial compression device, whereas the most frequently used means of obtaining haemostasis at the time of our audit was manual, otherwise known as digital compression. Practice at this centre had altered to accommodate the increased number of referrals during the course of the audit, so that nurses were the key clinicians involved in achieving haemostasis post-sheath removal through manual compression of femoral arterial sites. All were required to undertake specific training and achieve competence through supervised practice. It is possible that this may have contributed to the reduction in haematomas noted in the second group of patients as suggested by Lim *et al*. (1997) but must remain unsubstantiated at present as this aspect was not formally assessed within the audit.

When considering patient comfort in relation to reduced bed-rest times, it must be remembered that only bed-rest times post-sheath removal were examined. Thus, some patients may have experienced prolonged bed rest previously if sheaths remained *in situ* for long periods post-procedure due to unstable angina symptoms or problems with anticoagulopathy.

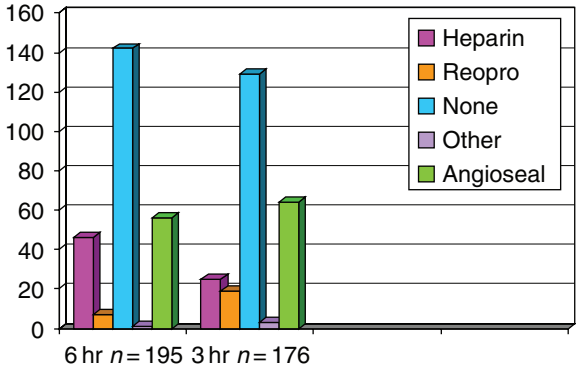


Figure 2 Complications graph

Clinical practice in this area of cardiology changes rapidly in response to empirical research around adjuncts to interventional techniques, and nursing care must remain dynamic enough to respond to such changes. Guidance from the National Institute for Clinical Excellence regarding increasing the indications for using Glyco Protein IIb/IIIa inhibitors in high-risk patients has the potential to increase sheath-site complication rates due to increased anticoagulation (NICE, 2002). This in turn has led to an increase in the use of closure devices such as collagen plug and suture inserts (Crocker *et al*., 2002; Lee *et al*., 2002; Koreny *et al*., 2004) plus further reliance on pneumatic pressure devices. It will be an important aspect of ongoing monitoring to evaluate the effects of these changes on complication rates and bed-rest times by means of further audits. It is recommended that this work be integral to the procedure monitoring requirements of the British Cardiac Interventional Society (BCIS) to ensure compliance and enable wider comparison across the UK.

An area of interest not explored here or within previous literature concerns how standards of care are agreed in centres that are just establishing an angiography or angioplasty service in line with meeting the government's NSF targets. One of the aims of introducing the NSF was to enable equitable provision of resources; yet it is apparent from the literature review and benchmarking exercise that care practices varied significantly throughout the UK and indeed Europe with regard to length of bed-rest post-femoral arterial sheath removal at the time of this audit. Additionally, there may be issues around training of staff to care for patients' post-sheath removal or indeed, training them to remove the sheaths. At the time of the clinical benchmarking activity, only nurses or doctors were involved in removing femoral arterial sheaths, mostly using manual, digital compression without the assistance of pneumatic compression devices. As previously mentioned, all healthcare professional's roles in this area are the subject of much interest currently and whilst draft competencies required for certain aspects of working in the cath lab environment are being developed, there does not appear to be any commensurate work-stream developing training to achieve the competencies. This is an important aspect of practice development to consider in ensuring that high standards of care are established and maintained alongside the increased demands on services. Effective assessment of patients prior to their procedure may also contribute to ensuring that additional complications are not experienced due to issues such as peripheral vascular disease increasing risk of woundsite complications or potential problems due to pharmaceutical additions or reductions (for example patient on long-term anticoagulation therapy with warfarin receiving inappropriate, additional anticolagulopathy). Such aspects of care were beyond the remit of this audit but are worthy of further exploration as, anecdotally, good preparation seems to lead to fewer cancellations. Further clinical benchmarking work may also be helpful to identify which healthcare professionals undertake these roles and what training they receive to ensure they are competent to do so.

Limitations

Our audit tool was designed specifically for this project and therefore had not been subject to the rigorous testing that other measurement tools are subject to. It is hoped that it can be refined in line with the BCIS's monitoring of complication rates for future use.

Results were initially presented internally but were felt by other staff to be too important not to share, so were presented at national and international conferences. From here we were encouraged to prepare our findings for publication, hence the time delay from completion of data collection to publication. The change to 3h bed rest was adopted following our initial presentation in 2001, but there has been no formal re-evaluation of complication rates since this time, hence our recommendations.

CONCLUSION

Seeking to establish evidence-based care is one of the essential steps involved in building a quality service for patients (Clarke, 2001) through promoting clinical effectiveness (NHSE, 1996). Reducing the amount of bed rest required post-femoral arterial sheath removal from 6 to 3h has not increased complication rates in patients following angiography or angioplasty. Clinical practice changed in response to these results so that usual care is now 3h bed rest. Clinical audits such as this demonstrate that nurses can play an important role in ensuring that patient care is evidence-based and cost-effective. Responding to the Government targets set to increase numbers of patients referred for both diagnosis and treatment of coronary artery disease has proved challenging in practice. Ensuring that patients are comfortable whilst maintaining a safe environment for them in a timely manner requires skilled practitioners delivering effective, substantiated care. Results from this audit, combined with expanding our nurse-led preadmission clinics, have allowed us to increase numbers of patients able to attend as day cases, thus enabling more effective use of our acute hospital beds for patients requiring more extensive treatment.

WHAT IS KNOWN ABOUT THIS TOPIC

- Current practice suggests that following removal of a femoral arterial sheath patients must remain on bed rest, but the length of time lying supine and sitting up in bed is variable
- Studies reviewing this subject previously have focused only on patients following cardiac angiography, not angioplasty
- Most of these studies were performed outside the UK

WHAT THIS PAPER ADDS

- Clinical benchmarking at the outset identified large variations in practice around the UK
- The audit of complications post-arterial sheath removal suggests that it is safe to mobilize after 3 h bed rest whether the patient has had an angiogram or angioplasty procedure
- Clinical practice at one local centre changed on the basis new findings

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APPENDIX 1: AUDIT TOOL

Professional interest group

Audit of wound sites post-angiogram and percutaneous transluminal coronary angioplasty (PTCA) with angioseal implantation date

		Procedure														
Sex				A		Anticoagulation						Wound condition on leaving department				
M	F	CC	PTCA	Y	N	Heparin	Repro	Sheath size	Time started pressing	Time stopped pressing	Total time in minutes pressing	Dry	Haematoma	Ooze	Glistening	

CC, cardiac catheter; A, angioseal used

Cath lab

Wound condition on arrival to ward						Wound condition on arrival to ward				Complications		
Dry	Haematoma	Ooze	Glistening	Flat bedrest (h)	45° bedrest (h)	Dry	Haematoma	Ooze	Glistening	Haematoma	Vaso-vagal episode	Bleeding from wound site

Haematoma ≥ 5cm