INTERVENTIONAL CARDIOLOGY AND SURGERY

Mitral repair best practice: proposed standards

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Objectives: To define best practice standards for mitral valve repair surgery. **Design:** Development of standards for process and outcome by consensus. **Setting:** Multidisciplinary panel of surgeons, anaesthetists, and cardiologists with interests and expertise in caring for patients with severe mitral regurgitation.

Main outcome measures: Standards for best practice were defined including the full spectrum of multidisciplinary aspects of care.

Results: 19 criteria for best practice were defined including recommendations on surgical training, intraoperative transoesophageal echocardiography, surgery for atrial fibrillation, audit, and cardiology and imaging issues.

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Conclusions: Standards for best practice in mitral valve repair were defined by multidisciplinary consensus. This study gives centres undertaking mitral valve repair an opportunity to benchmark their care against agreed standards that are challenging but achievable. Working towards these standards should act as a stimulus towards improvements in care.

f severe mitral regurgitation is left untreated there is a risk that limiting symptoms and irreversible left ventricular dysfunction will develop. Timely corrective surgery reduces this risk.1 2 Degenerative disease is the most common cause of mitral regurgitation in the Western world and in experienced hands most cases can be treated successfully by mitral repair, which carries a clear advantage over mitral valve replacement.²⁻⁵ However, in Europe about 50% of patients with mitral regurgitation are treated with valve replacement rather than repair and it is estimated that about one third of these replacements are performed because of a lack of local availability of reconstructive surgery.6 Current criteria recommend mitral valve repair when patients develop class II symptoms, any deterioration in left ventricular function, or an end systolic diameter ≥ 4.5 cm.⁷ ⁸ Recent evidence from a large single centre study suggests that the best outcomes after repair of severe degenerative mitral regurgitation are achieved in asymptomatic or minimally symptomatic patients, who are selected for surgery soon after diagnosis on the basis of quantitative echocardiography.² If mitral repair surgery is to become routine, and especially if it is to be proposed for asymptomatic patients, valve repair programmes will need to be subjected to close scrutiny to ensure that high standards of practice are achieved.

Modern care of patients with mitral regurgitation is a multidisciplinary, multiagency activity, involving primary, secondary, and tertiary care, cardiologists, cardiac surgeons, anaesthetists, and cardiac imaging technicians. We have used a multidisciplinary panel to define standards of best practice for the processes and outcomes desirable for high quality care.

METHODS

We have developed standards for best practice by an analysis of the literature followed by consultation with a multidisciplinary panel to achieve consensus. We should emphasise that these are not referral or practice guidelines but a series of criteria that were felt to be desirable when providing a high quality mitral valve repair service. The standards were meant to be challenging but achievable. The panel was selected informally to be made up of clinicians with subspecialist interest and expertise in caring for patients with mitral regurgitation and comprises eight surgeons, three cardiologists, and two anaesthetists. All of the panel are coauthors. Appendix 1 gives the professional credentials of the panel members.

We addressed the following specific questions:

- Is it possible to define standards for best practice for mitral valve repair surgery by consensus of a multidisciplinary panel?
- If so, what aspects of referral and patient management are important?
- What institutional and organisation criteria are required to achieve best practice?
- What outcomes are expected after surgery?
- Is it possible to define training requirements and caseload volume thresholds for best practice?

The standards were produced and given levels of evidence according to the American College of Cardiology (ACC)ACC/ American Heart Association (AHA) format⁹:

- Level of evidence A: data are derived from multiple randomised clinical trials or meta-analyses.
- Level of evidence B: data are derived from a single randomised trial or from non-randomised studies.
- Level of evidence C: only consensus opinion of experts, case studies, or standards of care are available.

RESULTS

It was possible to gain consensus of the panel on standards for best practice. Nineteen recommendations were made, subdivided into six areas: surgical training, intraoperative

Abbreviations: ACC, American College of Cardiology; ACTA, Association of Cardiothoracic Anaesthetists; AF, atrial fibrillation; AHA, American Heart Association; BSE, British Society of Echocardiography; EACTA, European Association of Cardiothoracic Anaesthesiologists; EAE, European Association of Echocardiography; TOE, transoesophageal echocardiography

Table 1 Best practice standards for mitral repair services

Criteria

- A. Surgical training
- 1. Surgeons performing mitral valve repair surgery should have undergone specific training in mitral valve repair, including participation in established repair workshops
- 2. Surgical skills laboratories should be available to develop, maintain, and teach surgical technique
- B. Intraoperative echocardiography issues
 1. Mitral valve repair should be undertaken only with availability of high quality intraoperative TOE
- Anaesthetists for mitral repair surgery should have expertise in intraoperative TOE and should hold UK (ACTA/BSE), European (EACTA/EAE), or US (NBE) accreditation. Where the intraoperative echocardiography service is provided by cardiologists, they should be similarly accredited
- C. Surgery for atrial fibrillation
- Hospitals should provide surgical ablation of atrial fibrillation
- 2. Surgeons undertaking mitral valve repair surgery should have
- expertise in surgical ablation of atrial fibrillation
- D. Volume thresholds
- 1. Surgeons undertaking mitral repair surgery should be doing more than 25 repairs each year
- 2. Hospitals undertaking mitral repair surgery should be doing more than 50 repairs each year
- E. Audit
- 1. Surgeons undertaking mitral repair surgery should subject their results to regular audit
- 2. Audit of mitral valve surgery should include an analysis of the mitral
- procedures stratified by aetiology 3. Audit should include an analysis of mortality, residual regurgitation on discharge, recurrence of regurgitation, and reoperation rates
- 4. Mortality for isolated repairs on degenerative disease should be less than 1% and five year reoperation rate should be less than 5%.
- 5. Audit data on results of mitral valve repair should be available to patients and referring cardiologists
- F. Cardiology and imaging issues
- 1. Local guidelines for referral of patients should be available to all cardiologists
- 2. Hospitals undertaking mitral repair surgery should have at least one designated cardiology consultant with a subspecialist interest in mitral valve disease
- 3. Validated quantitative echocardiography should be routinely available
- 4. Patients after mitral repair should have follow up echocardiography before discharge from hospital or at the first postoperative outpatient visit to quantify residual regurgitation
- 5. Both preoperative and perioperative echocardiography data should be regularly audited to ensure quality control and to provide continuing education
- 6. Multidisciplinary meetings should be held focusing on mitral repair including discussion of discrepancies between echocardiographic and surgical findings

ACTA, Association of Cardiothoracic Anaesthetists; BSE, British Society of Echocardiography; EACTA, European Association of Cardiothoracic Anaesthesiologists; EAE, European Association of Echocardiography; NBE, National Board of Echocardiography; TOE, transoesophageal echocardiography

transoesophageal echocardiography (TOE), surgery for atrial fibrillation (AF), volume thresholds, audit, and cardiology and imaging issues. The standards in these six groups are given below along with the justifications for their inclusion. Table 1 give the 19 standards.

Surgical training

Surgeons undertaking mitral valve repair surgery should have undergone specific training in mitral valve repair, including participation in established repair workshops. Surgeons should have access to surgical skills laboratories to develop, maintain, and teach surgical techniques.

Training for surgeons is an essential prerequisite for high quality mitral repair services with the need for both preconsultant training and ongoing development after consultant appointment. To ensure optimal exposure of surgical trainees to mitral repair procedures, individual units and training programmes should have processes to maximise

training opportunities, and training for designated surgeons should continue in a structured way after consultant appointment.¹⁰ There are several accepted surgical courses for basic and advanced valve repair and we feel that surgeons undertaking valve repair should have attended such events. There is, for example, a European "master of valve surgery" programme, sponsored by industry, which requires attendance at basic, intermediate, and advanced workshops, but we feel that this is only one way of gaining appropriate subspecialist training. These courses are largely observational, with little opportunity to develop surgical techniques under instruction or by self directed learning. We therefore consider that structured use of a surgical skills laboratory for initial training and continued development is best practice. We accept that neither educational courses nor skills laboratories will guarantee high quality surgery, but we feel both may contribute to it. There is no programme of accreditation for mitral repair surgeons in the UK but we feel that this may be beneficial in the future.

Intraoperative TOE

Mitral valve repair should be undertaken only with availability of high quality intraoperative TOE. Anaesthetists for mitral repair surgery should have expertise in intraoperative TOE and should hold UK (Association of Cardiothoracic Anaesthetists (ACTA)/British Society of Echocardiography (BSE)), European (European Association of Cardiothoracic Anaesthesiologists (EACTA)/European Association of Echocardiography (EAE)), or US (National Board of Echocardiography) accreditation. Where the intraoperative echocardiography service is provided by cardiologists, they should be similarly accredited.

Intraoperative TOE is essential for assessing the pathological condition and function of the mitral valve both before and after mitral repair. Failure to use intraoperative TOE is associated with a higher incidence of reoperation.¹¹ The ACTA and BSE have developed an accreditation process with an examination, supervised learning, and practice and completion of a logged evidence of practice.¹² There is now also a European accreditation scheme backed by the EAE and EACTA. We feel that accreditation from one of these organisations would be best practice for anaesthetists or cardiologists giving an intraoperative echocardiographic opinion.

Surgery for AF

Hospitals undertaking mitral repair surgery should offer surgical ablation for AF, and surgeons should have expertise in these techniques.

Many patients with mitral valve disease develop AF. AF is a predictor of heart failure, heart failure related death, and all cause death in patients after mitral valve surgery.13 Return of AF after mitral valve surgery is a major risk for cerebrovascular accident.14 Left atrial ablation with radiofrequency or other energy sources has been shown to be an effective procedure at restoring sinus rhythm in around 85% of cases.15-18 It is safe, and sinus rhythm is maintained during mid term follow up. Electrical restoration of sinus rhythm is associated with a recovery of atrial contraction and a decrease in atrial volume.¹⁷ Although benefits of surgical treatment of AF have not been shown in randomised studies, we feel that the existing evidence suggests that surgical ablation should be offered to those patients undergoing mitral valve surgery with established or paroxysmal AF. In the UK there are no clear funding streams determined for remunerating organisations for the cost of AF surgery and it is not offered in all centres. Surgeons performing AF surgery should have undergone appropriate training in these procedures.

Volume thresholds

Surgeons undertaking mitral repair surgery should be doing more than 25 repairs each year and hospitals should be doing more than 50 repairs each year.

It is clear from the surgical literature that there is a correlation between volume and outcome for some surgical procedures including paediatric cardiac surgery, coronary artery bypass surgery, carotid endarterectomy, other vascular surgery, hip replacement, and several cancer operations.^{19–28} This association applies to both institution and individual volumes. Many studies have analysed outcomes after dividing surgeons into low, medium, and high volume groups. The annual volume of surgery required to be a "high volume" surgeon varies greatly with different procedures ranging from 10 abdominal aortic aneurysm repairs to 30 carotid endarterectomies, 50 hip replacements, 75 paediatric cardiac surgical operations, and up to 200 coronary bypass operations. No data on volume–outcome associations for mitral valve repair are available.

A further influence on any decisions about ideal surgical volumes is that modern health care requires not only that high quality care be given but also that high quality health care can be demonstrated to patients, health service managers, the media, politicians, and other clinicians.²⁹ We therefore felt it appropriate to include a volume threshold for mitral valve repair, which would allow sufficient numbers to be generated for mortality and reoperation rates to be demonstrable with some confidence over a period of several years. Higher volume units and surgeons will have more power to reassure referring cardiologists of good outcomes to encourage early referral of less symptomatic patients. After considering all factors we decided on volume threshold recommendations of 25 repairs for each surgeon and 50 repairs for each hospital yearly. These are identical to the institutional volume thresholds set for major urological malignancy in the UK.³⁰ Some types of mitral repair (such as pan-leaflet prolapse in Barlow's disease and complex repeat repair) present a particular technical challenge and require a high level of judgement and expertise. We feel that the best results in these cases are likely to be achieved by surgeons who are undertaking a very high volume of surgery, and a regional referral practice to "super-specialists" may prove to give the best results.31

Some surgeons may argue that any surgeon can treat mitral regurgitation, particularly that caused by straightforward prolapse of the middle segment of the posterior leaflet, and that the volume thresholds we have recommended here are not necessary. We would disagree for several reasons. We feel that there is a significant learning curve for this type of surgery and in our experience the results for all mitral repair continue to improve, even after a considerable volume of surgery. We are concerned that the quality of preoperative echocardiographic diagnosis is not always accurate, and that patients referred for straightforward mitral repair may have more complex disease requiring specific techniques to achieve satisfactory repair. Lastly we feel that the arguments for low volume mitral repair surgery may be made by clinicians who are interested in maintaining a varied practice, and that this can be at odds with achieving best results for patients. By concentrating mitral valve surgery in the hands of a small number of specialists there is a risk of "deskilling" other surgeons in mitral valve surgery who may need to retain these skills for rare nonelective or unexpected situations. We accept that this is a potential downside of our recommendations but feel that it would be more than compensated for by better care for the majority of patients with mitral regurgitation.

Audit

Surgeons undertaking mitral repair surgery should subject their results to regular audit, which should include an analysis of the mitral procedures stratified by aetiology. Mortality for isolated repairs on degenerative disease should be less than 1% and the five year reoperation rate should be less than 5%. Audit should include an analysis of residual and recurrent regurgitation after repair. Audit data on results of mitral valve repair should be available to patients and referring cardiologists.

Audit is an essential part of ensuring good services, and demonstrating satisfactory operative outcomes to cardiologists and patients is an important part of encouraging early referral. Numerous large studies have followed up patients who have undergone mitral repair. Some include patients who have had surgery for degenerative disease and others focus on ischaemic mitral regurgitation.^{32–40} It is clear that the outcome of surgery depends on aetiology-mortality is higher among patients with ischaemic disease and when developing standards it is important to discriminate for this. It is also clear that the long term outcome of mitral repair for degenerative disease depends on the type of leaflet abnormality—recurrence of regurgitation is considerably more common after surgery for anterior leaflet than for posterior leaflet abnormalities.^{32–38} In defining our standards we have specified mortality outcomes for isolated surgery for degenerative disease and have suggested an acceptable mortality of less than 1% and a reoperation rate of less than 5% at five years. We recognise that if only posterior leaflet disease is corrected then the recurrence rate should be low, and if a high number of complex anterior or bileaflet procedures are performed a higher reoperation rate may be acceptable. We also accept that if patients with degenerative disease are referred late, once there has been significant deterioration in left ventricular function, observed operative mortality may be higher.

It is clear that the incidence of recurrent regurgitation after surgery is higher than that of reoperation.³³ Best practice audit would include robust assessment of residual or recurrent regurgitation. The incidence would also depend on the initial aetiology of the regurgitation and the type of mitral repair.

Cardiology and imaging issues

Hospitals undertaking mitral repair surgery should have at least one designated cardiology consultant with a subspecialist interest in mitral valve disease. Local guidelines for referral of patients should be available to all cardiologists. Validated quantitative echocardiography should be routinely available. Both preoperative and perioperative echocardiographic data should be regularly audited to ensure quality control and to provide continuing education. After mitral repair patients should have follow up echocardiography to quantify residual mitral regurgitation either before discharge from hospital or at the first postoperative outpatient visit. Multidisciplinary meetings should be held focusing on mitral repair, including discussion of discrepancies between echocardiographic and surgical findings.

Much of the attention for cardiology in recent years has focused on ischaemic heart disease, but we feel that subspecialist interest in valve pathology in general and mitral valve disease in particular is important if services are to develop. The clinical and echocardiographic assessment of patients with mitral regurgitation is not always straightforward. Symptoms may develop insidiously and may be missed unless looked for specifically. Echocardiography is key to the assessment of both the aetiology and severity of regurgitation. It also provides important clinical information regarding left ventricular size and function, left atrial size, and pulmonary arterial pressure. A recent single centre study has shown that patients with degenerative regurgitation and an effective regurgitant orifice area of more than 40 mm² should be considered promptly for surgery, irrespective of their level of

symptoms or ventricular function.² Assessment of effective regurgitant orifice area or regurgitant volume by quantitative echocardiography is technically demanding and requires considerable skill and practice if meaningful and reproducible results are to be obtained.⁴¹ Anecdotal experience suggests that few units in the UK are routinely using these techniques and most are relying instead on semiquantitative estimation of the severity of regurgitation. Any move towards surgery in less symptomatic patients demands that assessments be accurate and objective, and we feel that quantitative echocardiography should become the norm for the assessment of all patients with mitral regurgitation including those with ischaemic mitral regurgitation where assessment may be particularly difficult. If this is to happen assessments should be carried out by experienced echocardiographers with specific training in the techniques with regular peer review of studies to ensure consistency of interpretation. High quality TOE is also required and feedback from surgical findings is important. For these reasons we advocate that all referrals generated in a centre be channelled through a single cardiologist working closely with the surgeons, anaesthetists, and echocardiography department.

We feel that digital archiving and retrieval of echocardiographic studies, including quantitative data, should be encouraged so that serial comparison of echocardiographic data is readily available. This is particularly important in patients with left ventricular dysfunction or residual mitral regurgitation after surgery. Recorded measurements should include left ventricular size and function, left atrial volume, valve morphology, effective regurgitant orifice area/regurgitant volume, and pulmonary artery pressure. We feel these measurements should be made routinely on all patients who have undergone mitral repair, either before discharge from hospital or at the first follow up outpatient appointment.

For those centres with the availability of cardiac magnetic resonance imaging, this may be an acceptable alternative for measuring the severity of regurgitation but also requires significant local expertise. Any move towards earlier treatment for less symptomatic patients is not yet reflected in published guidelines.^{2 7 8} We believe therefore that local guidelines should be available for referring cardiologists, which incorporate the existing literature set against local surgical and imaging practices.

All of these standards are level of evidence C.

DISCUSSION

Statement of principle findings

This study has shown that it is possible to define best practice standards for processes and outcomes for mitral repair services by consensus of a multidisciplinary group of clinicians. These standards should act as a structured stimulus for improvement for centres undertaking mitral valve repair.

Strengths and weaknesses of the study

We are not aware of any existing best practice standards for mitral repair. We have used a multidisciplinary panel of enthusiasts to define standards by consensus. All panel members have experience and expertise in caring for patients with mitral regurgitation. The panel all have established mitral repair practices and can potentially be criticised for producing standards that reinforce their own views and interests, but we feel that our analysis of the existing literature and the multidisciplinary approach to the development of these standards gives them validity.

Strengths and weaknesses of the study compared with other studies

There are accepted AHA/ACC guidelines for management of valvar heart disease.7 European guidelines for patients with

asymptomatic disease have been published.⁸ While these give guidance about referral and acceptance for surgery, they do not address issues surrounding institutional processes and outcomes, nor have they considered aspects of individual training and volume thresholds.

Our best practice standards are based on an analysis of the available literature, backed up by consensus clinical opinion. There is little evidence from randomised studies to inform these standards and so all the recommendations are level of evidence C and as such will carry less weight than other guidelines that may be based on higher levels of evidence. It has proved relatively easy to gain consensus on these standards for this study, indicating a common thinking between several specialist surgeons, cardiologists, and anaesthetists. We accept that some of our recommendations, particularly those on subspecialisation and volume thresholds, may prove controversial, but we feel that they are a useful benchmark, which should stimulate debate and subsequent improvement. We also feel that a precedent has been set for these types of standards by political initiatives in the UK in areas such as urology and breast surgery.30 42

Meaning of the study

We have defined standards for best practice by consensus of a multidisciplinary professional group of surgeons, anaesthetists, and cardiologists. Many of these standards focus on institutional, rather than individual, process issues. It will be possible to audit against these standards. We feel that defining and publishing these standards should stimulate units providing mitral repair to improve the processes of care.

Unanswered questions and future research

We do not know whether defining standards for best practice for a subspecialist surgical speciality will improve standards. As most of the standards we have defined lack a high level of evidence to justify them, we cannot be sure that they will be embraced by the profession. More evidence on volumeoutcome associations for mitral repair surgery may further inform the debate. A comparative audit of several hospitals against these criteria would give valuable information and further useful data may come from national audit projects. Any action hospitals may take as a result of publication of these standards will be discretionary; however, professional societies and associations may wish to stimulate improvements by introducing specific accreditation schemes for subspecialist cardiac surgery and cardiology.

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Competing interests: Appendix 1 give the various academic and political appointments held by the authors.

BB has attended various medical meetings sponsored by heart valve/ repair ring manufacturers and has received occasional honoraria for lectures/teaching on mitral valve repair from Edwards Lifesciences and Medtronic

TLH has attended various medical meetings sponsored by heart valve/ repair ring manufacturers and has conducted research into cardiomyoplasty and lung preservation sponsored by valve manufacturers.

CM has attended various meetings and symposia sponsored by heart valve manufacturers and has received occasional honoraria from St Jude Medical for organising and teaching on nurse study days.

SH has attended various medical meetings sponsored by heart valve/ repair ring manufacturers

UvO has received occasional honoraria for lectures/teaching on mitral valve repair and surgery for atrial fibrillation from Edwards Lifesciences and Medtronic

SL has attended various medical meetings sponsored by heart valve/ repair ring manufacturers and has received occasional honoraria for lectures/teaching on mitral valve repair from Edwards Lifesciences and Medtronic

JC has received open grants from various valve manufacturing companies for author-initiated research projects, and has had consultancy agreements with various valve manufacturers. He has delivered academic lectures about replacement heart valves at meetings organised by cardiologists or cardiac surgeons some of which are sponsored by valve manufacturing companies. He sits on the BSI and ISO committees on replacement heart valves and is on the editorial panel of the *Journal* of Heart Valve Disease, the International Journal of Clinical Practice, and the British Journal of Cardiology. He is involved in setting and maintaining standards in echocardiography for individuals and departments under the auspices of the British Society of Echocardiography, British Cardiac Society and Healthcare Commission.

NM runs an annual echo course, co-directed by Philips Medical Systems, for which he receives a Course Directors fee, has received honoraria from Philips and GE Medical for lectures/teaching in echocardiography, has received honoraria from various pharmaceutical companies for lectures to cardiologists/trainees and GPs and has conducted research supported by Medtronic and Edwards Inc

SR runs an annual echo course, co-directed by Philips Medical Systems, for which he receives a course director fee and has received honoraria from Philips for lectures/teaching

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Contributor	Appointment	Other roles and potential conflicts of interest
Ben Bridgewater	Consultant Cardiac Surgeon, South Manchester University Hospitals Trust	Member Northwest Regional quality improvement programme in cardiac interventions; Member of joint Society of Cardiothoracic Surgeons, Healthcare Commission, Department of Health group defining national cardiac surgical audit
Tim Hooper	Consultant Cardiac Surgeon, South Manchester University Hospitals Trust	
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Simon Ray	Consultant Cardiologist, South Manchester University Hospitals Trust	Council Member, BSE

ACTA, Association of Cardiothoracic Anaesthetists; BSE, British Society of Echocardiography; EACTA, European Association of Cardiothoracic Anaesthesiologists; EAE, European Association of Echocardiography; NBE, National Board of Echocardiography; SCTS, Society of Cardiothoracic Surgeons of Great Britain and Ireland; TOE, transoesophageal echocardiography.

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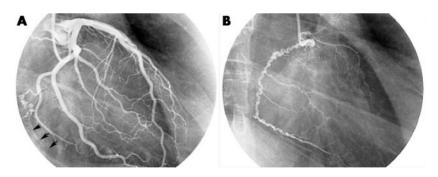
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Corkscrew appearance in the right coronary artery in a patient with Buerger's disease

44 year old man with suspected coronary artery disease was admitted to our hospital. He had been diagnosed with Buerger's disease, and both his legs had been amputated at the age of 30. Although the patient had no coronary risk factors except cigarette smoking and no history of chest pain, an admission ECG showed abnormal Q waves in leads II, III, and aVF and inverted T waves in leads III and aVF. Echocardiography revealed slight hypokinesis in the inferior wall of the left ventricle. Cardiac catheterisation was performed via the right brachial artery. A left coronary arteriogram revealed the normal left coronary system with collateral circulation to the distal right coronary artery (panel A). A right coronary arteriogram showed a 99% stenosis with delay in the distal portion of the artery and a "corkscrew appearance" from the origin of the artery until the mid-portion of it (panel B). A left ventriculogram revealed slight hypokinesis in the inferior wall with an ejection fraction of 70%. An aortogram showed the intact thoracic aorta including its major branches



Coronary arteriograms. (A) The left coronary arteriogram shows an intact left coronary system and collateral circulation to the right coronary artery (arrow). (B) The right coronary arteriogram shows a stenotic lesion with a "corkscrew appearance"

The corkscrew appearance observed in our case has not been previously reported in Buerger's disease. Further investigations are desirable to clarify the pathogenesis of this unique appearance.

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