

A prospective randomised comparison of minor surgery in primary and secondary care. The MiSTIC trial

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Executive summary

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Executive summary

Objectives

The objective of this study was to determine whether there is equivalence in the competence of GPs and hospital doctors to perform a range of elective minor surgical procedures, in terms of the safety, quality and cost of care.

The aims were:

- to conduct a randomised controlled equivalence trial of minor surgery in two settings
- to collect data on quality of surgery, patient satisfaction, patient safety and cost of procedure in two settings
- to review data from this trial and from other sources in order to consider future direction and future research in this area.

Methods

Design

This prospective randomised controlled equivalence trial was undertaken in consenting patients presenting at general practices and needing minor surgery.

Setting

The study was conducted in the south of England. At the time of this trial, minor surgery provision was provided mainly via a fee for service contract with general medical practitioners, with some serious pathology treated in hospital.

Participants

Participants were consenting patients presenting at general practices. They all needed minor surgery in specified categories and the recruiting doctor felt able to offer treatment or to be able to refer to a colleague in primary care.

Interventions

Patients were randomised, on presentation to their GP, to either treatment within primary care or treatment at their local hospital. Evaluation was by assessment of clinical quality and safety of outcome, supplemented by examination of patient satisfaction and cost-effectiveness.

Main outcome measures

The primary measure was surgical quality assessed by blinded assessment of wound appearance, between 6 and 8 weeks postsurgery, by two independent observers, using photographs of wounds. Secondary measures included satisfaction with care, which was obtained by means of a patient questionnaire; safety of surgery in terms of recognition of and appropriate treatment of skin malignancies, obtained by an examination of histological material supplied and cross-referencing with referral forms from GPs; and resource use and implications.

Results

In total, 568 patients were recruited (284 primary care, 284 hospital) and randomised by 82 GPs. Altogether, 637 skin procedures plus 17 ingrowing toenail procedures were performed (313 primary care, 341 hospital) by 65 GPs and 60 hospital doctors. Surgical quality was assessed for 273 (87%) primary care and 316 (93%) hospital lesions. Mean visual analogue scale score in hospital was significantly higher than that in primary care [mean difference = 5.46 on 100-point scale; 95% confidence interval (CI) 0.925 to 9.99], but the clinical importance of the difference was uncertain. Patients tended to be more satisfied with procedures in primary care and to report less inconvenience from their procedure. Hospital doctors were better at achieving complete excision of malignancies, with a difference that approached statistical significance [7/16 GP (44%) versus 15/20 hospital (75%), $\chi^2 = 3.65$, $p = 0.056$]. The proportion of patients with post-operative complications was similar in both groups. The mean cost for hospital-based minor surgery was £1222.24 and for primary care £449.74. Using postoperative complications as an outcome, both effectiveness and costs of the alternative interventions are uncertain. Using completeness of excision of malignancy as an outcome, hospital minor surgery becomes more cost-effective.

The 705 skin procedures undertaken in this trial generated 491 lesions with a traceable histology report: 36 lesions (7%) from 33 individuals were

malignant or premalignant. Chance-corrected agreement (kappa) between GP diagnosis of malignancy and histology was 0.45 (95% CI 0.36 to 0.54) for lesions and 0.41 (95% CI 0.32 to 0.51) for individuals affected by malignancy. Sensitivity of GPs for detection of malignant lesions was 66.7% (95% CI 50.3 to 79.8) for lesions and 63.6% (95% CI 46.7 to 77.8) for individuals affected by malignancy.

Conclusions

The quality of minor surgery carried out in general practice is not as high as that carried out in hospital, using surgical quality as the primary outcome, although the difference is not large. Patients are more satisfied if their procedure is performed in primary care, however, largely because of advantages in terms of convenience. However, there are clear deficiencies in the ability of GPs to recognise malignant lesions, and there may be differences in completeness of excision when compared with hospital doctors.

The safety of patients is of paramount importance and this study does not demonstrate that minor surgery carried out in primary care is safe as it is currently practised. There are several alternative models of minor surgery provision worthy of consideration, including ones based in primary care that require all excised tissue to be sent for histological examination, or that require further training of GPs to undertake the necessary work. The results of this study suggest that a hospital-

based service is more cost-effective, but at the moment there is not the capacity in hospitals to take on the workload of minor surgery, and it would likely be unpopular with patients if it were to happen. It must be concluded that it is unsafe to leave minor surgery in the hands of doctors who have never been trained to do it. If the capacity to undertake the work is present in primary care, then the increased costs associated with training doctors to do it must be borne.

Suggestions for further research

Further work is required to determine GPs' management of a range of skin conditions (including potentially life-threatening malignancies), rather than just their recognition of them. Further economic modelling work is required to look at the potential costs of training sufficient numbers of GPs and GPs with special interests to meet the demand for minor surgery safely in primary care, and of the alternative of transferring minor surgery large-scale to the hospital sector. Different models of provision need thorough testing before widespread introduction.

Publication

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NIHR Health Technology Assessment Programme

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