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- Des Spence: Melanoma (*BMJ* 2011;343:d5477)

Identifying melanomas in primary care: can we do better?

Teaching best clinical practice shows more promise than a new technology

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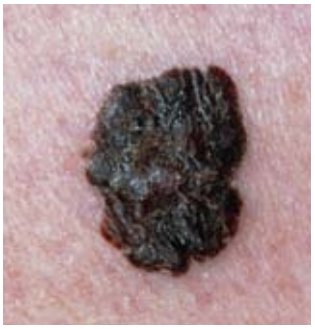
The prognosis for patients with melanoma depends on the stage of disease at diagnosis. In some European countries tumour thickness is much higher at presentation than in others, with consequent adverse effects on survival.[1] The thickness of tumours at presentation to secondary care in the United Kingdom is such that the overall survival at five years is around 80% for men and 90% for women.[2] Survival rates are higher in some countries, such as Australia, where excision of thinner tumours is more common.[3] Such better outcomes are thought to be due to higher levels of awareness among patients and general practitioners.

The incidence of melanoma continues to increase in many areas of the world, and greater awareness is needed so that the thickness of tumours at presentation is reduced without excessive increases in referral to secondary care. In the linked study (p 15),[4] Walter and colleagues tested a computerised diagnostic tool, the MoleMate system, as a means of increasing diagnostic accuracy and referral to secondary care for suspicious pigmented lesions.

Cancer referral guidelines have been developed in the UK to promote more appropriate referrals, and a recent audit in Scotland showed that the rate of appropriate referral for melanoma was low.[5] A total of 18 775 urgent, suspected cancer referrals were analysed from 516 general practices. Compliance with referral guidelines was 90.9%. The referral rate ranged from 3.7 to 24.0 per 1000 per annum; 30.8% of referrals were for patients aged under 50 years, yet this age group accounts for only 11.1% of all diagnosed cancers; 10.3% of referrals were for suspected melanoma, yet this cancer accounts for only 4.1% of new cancers. The proportion of patients correctly referred with suspected melanoma was 11.8%, compared with 61.7% for suspected leukaemia. The relatively high rate of referral for suspected melanoma and the relatively low positive pick-up rate reflect a lack of diagnostic confidence in primary care. This audit confirmed the findings of another study designed to investigate the appropriateness of referrals under the two week referral system for suspected cancers in the UK.[6] This study found that the proportion of melanomas and squamous cell carcinomas correctly referred was around 20%, and this rate did not improve after the introduction of targeted education.


JAMES STEVENSON/SPL
Early diagnosis requires awareness

The MoleMate system reported here is based on computerised analysis of light reflected by the skin. Several tools for detecting melanoma have been reported over the years, many of which have been based on dermoscopy. Although they are often viewed positively by patients, their high false positive rate has limited their use.[7]

The authors of the current study specifically tested the MoleMate tool as an aid to diagnosis in primary healthcare teams. Fifteen general practices in the east of England took part, and the appropriateness of referral was based on the proportion of patients referred who were either subsequently reviewed or had biopsies. All patients with a suspicious pigmented lesion were internally referred to a primary care physician who had been specially trained to follow best practice diagnostic guidelines, including the use of the seven point check list originally devised by Mackie[8]; for those randomised to the intervention they also applied the MoleMate system. Patients judged to have a benign lesion were offered a follow-up appointment three to six months later. Use of the MoleMate system did not result in more appropriate referrals than in the controls. Indeed use of this tool was associated with poorer recognition of benign lesions and a higher referral rate. It was interesting that patients and clinicians viewed the use of the technology positively, with increased diagnostic certainty in clinicians and reduced anxiety in patients.

The increased rate of referral in the MoleMate group is reminiscent of the observation that dermatologists show increased concern about borderline lesions when they first start to use dermoscopy to examine naevi. This increased referral rate might therefore have settled over time. Nonetheless, the technology was not of benefit. Although this is a negative study it is an important formal attempt to assess a new technology. Doctors and patients are often seduced by new technologies—in this study, both doctors and patients liked MoleMate, but the value of new technologies must be proved.

The authors compared the use of MoleMate technology to "best practice." Clearly best practice was an enhanced standard of care, and it is therefore not possible to compare referral rates with those in previous reports from the UK. However the outcomes for the control arm were encouraging and suggest that simple measures such as enhanced targeted education and internal referral could reduce inappropriate referrals. Diagnostic difficulty within primary care remains a problem and increased education of the public and primary healthcare teams is essential. In the UK, general practitioners have little training in dermatology, either as undergraduates or postgraduates, and this is probably reflected by the higher average stage of melanoma at presentation in the UK compared with many other European countries.

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- Why the GMC is right to appeal over life prolonging treatment (*BMJ* 2004;329:810)
- Assisted dying: are doctors in denial? (*BMJ* 2011;342:d3891)

Sanctity of life law has gone too far

Recent court ruling distorts healthcare provision and values and should be challenged

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Last year an English judge ruled, with the explicit approval of the president of the Court of Protection, that under the rules of that court all patients in a minimally conscious state must be referred to the Court of Protection if life prolonging treatment by artificial nutrition and hydration is to be withheld or withdrawn.[1-3] Moreover, the judge emphasised that in deciding whether such withdrawal would be in these patients' best interests it would "be wrong to attach significant weight" to their previously expressed values, wishes, and views unless these had been expressed in a legally valid and applicable advance decision. What should be given great "though not absolute" weight was the sanctity of life. The judge said (paragraph 230), "[given] the importance of the sanctity of life, and the fatal consequences of withdrawing treatment, and the absence of an advance decision that complied with the requirements previously specified by the common law and now under statute, it would in my judgment be wrong to attach significant weight to those statements made prior to her collapse."[1] Two aspects of this judgment are profoundly disturbing.

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Ruling gave undue weight to "sanctity of life"

The first concern is that the judge did not accord "significant weight" to the patient's previously expressed values, wishes, and views. The second is the judgment's logical implication that all decisions about starting or stopping life prolonging treatment, including the withholding or withdrawal of artificial nutrition and hydration, for all incapacitated patients should be brought to the Court of Protection, even though the judgment refers only to patients in a minimally conscious state. The logic is simple: if patients in a minimally conscious state who have not written a valid and applicable advance decision to reject life prolonging treatment must be referred to the court to prevent doctors inappropriately withholding or withdrawing such treatment, then logically those in a higher than minimal state of consciousness must be similarly protected. And if the previous values, wishes, and views about life prolongation of minimally conscious patients are to be accorded little weight against the principle of the sanctity of life unless those wishes have been expressed in a valid and applicable advance decision then, again logically, the same should apply to incapacitated patients whose state of consciousness is higher than minimal.

The stringent conditions in the Mental Capacity Act for an advance decision to refuse life prolonging treatment relate to a person's right to make that decision binding in law. But the act does not say that, unless those legal conditions are met, a person's ordinarily expressed views about being kept alive should be given little weight when others determine that person's best interests after he or she is permanently incapacitated. On the contrary, the act explicitly requires that the incapacitated person's previously expressed values, wishes, and views must be determined if possible.[4] Legal and philosophical analysis shows such requirements to be entirely consistent with the need to respect the person's previous autonomy when determining his or her best interests.[5]

The logical implications of this judgment threaten to skew the delivery of severely resource limited healthcare services towards providing non-beneficial or minimally beneficial life prolonging treatments including artificial nutrition and hydration to thousands of severely demented patients whose families and friends believe they would not have wanted such treatment. The opportunity cost will probably be reduced provision of indisputably beneficial treatments to people who do want them.

Medical advances have led to a vastly increased capacity to keep people alive without, in many cases, providing any real benefit to their health

Since Hippocratic times (at least) the primary goal of medicine has been to benefit people's health. Until recently, the exercise of doctors' very limited capacities to prolong life has almost always led to such benefits. Now, however, medical advances have led to a vastly increased capacity to keep people alive without, in many cases, providing any real benefit to their health. This recent judgment, and the practice directions of the Court of Protection, logically imply that doctors should no longer decide, in consultation with those who know their incapacitated patients, whether life prolonging treatment including artificial nutrition and hydration will be in their patients' best interests. Instead they must provide it until and unless the Court of Protection finds, exceptionally, that application of the principle of the sanctity of life is not in the particular patient's best interests. Unless this judgment is overturned or modified by a higher court it will gradually and detrimentally distort healthcare provision, healthcare values, and common sense.

Competing interests: None declared.

Provenance and peer review: Not commissioned; not externally peer reviewed.

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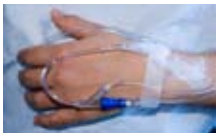

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Oxytocin is now widely accepted as the optimal choice for third stage prophylaxis because it is highly effective and has few side effects

Active management of the third stage of labour

Oxytocin is all you need

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The original description of active management of the third stage of labour had three components—delivery of a prophylactic uterotonic drug, early cord clamping and cutting, and controlled cord traction.[1] When randomised trials in the 1980s found that this package reduced the risk of severe postpartum haemorrhage by 70%,[2] active management was adopted widely. It was thought to be especially important in low resource settings, where more than 20 000 deaths occur each year as a result of haemorrhage.[3] In these settings, active management of the third stage has almost become a mantra for the safe motherhood movement.

But in the half century since active management was described, we have never known which component is the most important. Guidelines from around the world have varied widely in their selection of oxytocic agent, early cord clamping, cord traction, uterine massage, and cord drainage.[4] Controlled cord traction became popular only when it was incorporated into the active management package in 1962, and, although there were no major randomised trials of cord traction, it was thought to decrease the incidence of postpartum haemorrhage and retained placenta.[5]

The required evidence on cord traction appeared in March this year.[6] Gulmezoglu and colleagues from the World Health Organization's maternal health research network conducted a large multicentre controlled trial to examine the effect of active management of the third stage of labour with and without cord traction in more than 24 000 women.[6] All women received oxytocin (10 IU intramuscularly immediately after delivery) and had "delayed" cord clamping at one to three minutes. Participants then either underwent cord traction at the time of the first uterine contraction or the placenta was allowed to deliver with the aid of gravity and maternal effort only. The study had a non-inferiority design, and the team decided a priori that the two groups would be equivalent if the 95% confidence interval of the relative risk did not include a 30% or more increase in severe postpartum haemorrhage in the controlled traction group over the simplified regimen.

Compliance with the protocol was good, but in the simplified package group 6% of women still needed cord traction to deliver the placenta. Omission of cord traction from the active management package had no significant effect on the rate of severe haemorrhage (risk ratio 1.09, 95% confidence interval 0.91 to 1.31), but the difference in the risk of haemorrhage of more than 500 mL was of borderline significance (1.07, 1.00 to 1.14). Furthermore, given that the upper 95% confidence interval limit just crossed the pre-stated non-inferiority margin of 1.30, the authors had not proved that the two were equivalent. The time to placental delivery was halved in those having cord traction from 12 to six minutes (difference 6.5, 6.2 to 6.8), and this reduced the need for manual removal (1.45, 1.14 to 1.86). Further analysis of the results, however, showed that the difference in manual removal occurred in one country only. That country had experienced difficulty with recruitment and one of the two sites had been giving a combination of oxytocin and ergometrine for prophylaxis (in contravention of the study protocol). When the data were analysed without the results from that country (81% of all recruits were still included) no effect on the need for manual removal was seen (0.97, 0.68 to 1.37).

This study therefore showed that during active management of the third stage of labour cord traction has little, if any, part to play in reducing severe postpartum haemorrhage. It also showed that in sites using oxytocin alone for prophylaxis, cord traction reduced the length of the third stage by six minutes but had no effect on manual removal rates. The same may not be true when the combined oxytocin-ergometrine preparation is used.

The study is good news for maternity care providers, especially in low resource settings. Although cord traction is straightforward, it is often poorly done, and can result in uterine inversion or haemorrhage, or can cause the cord to snap. In settings where the training of birth attendants is brief and continuing support minimal, trainers are therefore likely to err on the side of caution and omit the cord traction step from the standard "oxytocin alone" active management package. The method will, however, still need to be taught because about one in 20 women who use maternal effort will require the procedure, and it may be important in settings that still use ergometrine based prophylaxis.

In settings where providers are confident that cord traction will be performed correctly, it will probably remain part of the package because it does no harm and could still have a small beneficial effect on blood loss.

Where does this leave the components of active management of the third stage of labour? Oxytocin is now widely accepted as the optimal choice for third stage prophylaxis because it is highly effective and has few side effects. Ergometrine (with or without oxytocin) may be slightly more effective but has side effects of vomiting and hypertension and is associated with retained placenta when given intravenously.[7] The second choice after oxytocin may therefore be misoprostol, which, although slightly less effective than oxytocin, has the benefits of stability and the option of oral or sublingual administration.[8]

The third component of the traditional package, early cord clamping, was removed from many active management packages some years ago. It seems to have no maternal benefit and reduces neonatal blood volume and infant iron stores in term babies by about 30%.[9] This effect is seen in resource rich and resource poor settings, and it persists to at least 4 months of age.[10] The hazards of early cord clamping seem to be increased in fragile premature fetuses—those who undergo early cord clamping on delivery have increased rates of blood transfusions and low grade intraventricular haemorrhages.[11]

It has taken 50 years since active management of the third stage of labour was first described for it to become clear that the oxytocic agent has the greatest effect. In settings where cord traction is currently being used it should continue to be part of the package. However, those looking to reduce deaths from postpartum haemorrhage in low resource settings will be delighted by these results because they show that high quality management of the third stage of labour does not require midwifery skills. Public health experts can therefore concentrate their efforts on simplified oxytocin injections (Uniject) and misoprostol alone.

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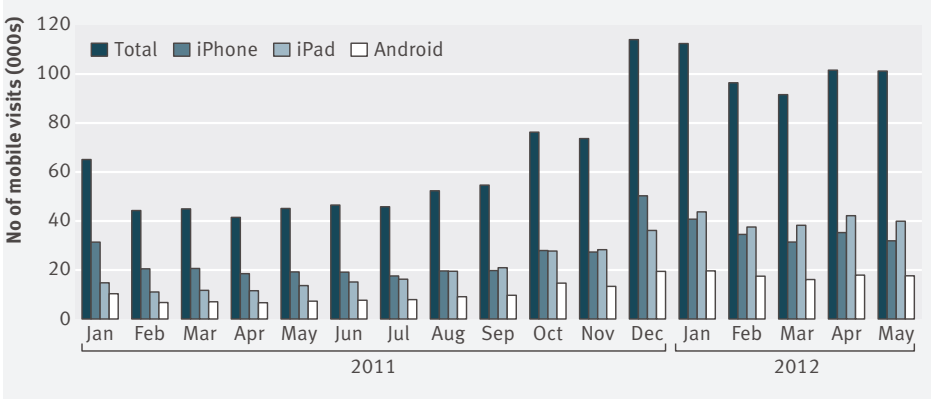

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