Jonathan R Olsen, John Gallacher, Vincent Piguet and Nick A Francis

Development and validation of the Molluscum Contagiosum Diagnostic Tool for Parents:

diagnostic accuracy study in primary care

Abstract

Background
Molluscum contagiosum (MC) is diagnosed by its distinct appearance. Parental diagnosis of MC may reduce anxiety and lead to reductions in healthcare consultations, and may be particularly useful in large-scale epidemiological studies. However, there are currently no published, validated tools allowing parental diagnosis of MC.

Aim
To develop and validate a tool for parental diagnosis of MC.

Design and setting
The Molluscum Contagiosum Diagnostic Tool for Parents (MCDTP) was developed and its diagnostic accuracy was compared with GP diagnosis in 12 GP surgeries in South Wales.

Method
Following development, which involved three phases with dermatologists, nurses, GPs, and parents, parents completed the MCDTP (index test) in the practice waiting room, and rated their confidence in their diagnosis. A GP then examined their child for MC (reference test). Test characteristics were calculated for all responders and for those who expressed being confident or very confident in their diagnosis.

Results
A total of 203 parents completed the MCDTP. The MCDTP showed a sensitivity of 91.5% (95% confidence intervals (CI) = 81.3 to 97.2) and a specificity of 88.2% (95% CI = 81.8 to 93.0) in all parents and a sensitivity of 95.8% (95% CI = 85.7 to 99.5) and a specificity of 90.9% (95% CI = 83.9 to 95.6) in parents who were confident or very confident in their diagnosis. The positive predictive value was 76.1% (95% CI = 64.5 to 85.4) and negative predictive value was 96.2% (95% CI = 91.4 to 98.8) for all parents.

Conclusion
The MCDTP performed well compared with GP diagnosis and is suitable for clinical use by parents and in population-based studies.

Keywords
dermatology; diagnostic tool; epidemiology; general practice; molluscum contagiosum; paediatrics.

INTRODUCTION

Molluscum contagiosum (MC) is a common skin condition that affects people of all ages, but is most prominent in children and the immunocompromised,[1–5] and is one of the 50 most prevalent diseases globally.[6] In children, MC is typically diagnosed in primary care following a clinical examination by a GP. MC typically has a distinct appearance of one or more umbilicated, smooth, flesh-coloured, dome-shaped lesion/s.[7] Unusual and more severe cases may be referred to a dermatologist.[8]

Although lesions are generally self-limiting, they can be extensive, cause itching and discomfort for children and anxiety for their parents, can result in scarring, and are sometimes treated with cryotherapy and other destructive modalities. They are also a frequent reason for parents to consult in primary care. In children there is an annual episode incidence rate between 95 and 172 per 10 000 population aged 1 to 14 years.[9]

Parents increasingly use the internet to try to diagnose skin lesions such as MC in their children. However, there are no published data on the validity of parental self-assessment. Tools using medical illustrations and text have been developed successfully to allow non-clinicians to screen for psoriasis,[10] and a range of other skin lesions.[11,12]

This study describes the development, using images and text, and validation of the Molluscum Contagiosum Diagnostic Tool for Parents (MCDTP).

METHOD

Development of the diagnostic tool

The development of the MCDTP was in three phases.

Phase 1: Establishing the key visual diagnostic characteristics of MC. Nine dermatologists, acting as key informants, were recruited to participate in semi-structured interviews to establish the key visual and descriptive diagnostic characteristics of MC. The results from the interviews were thematically grouped into four categories: history and population, appearance, site, and symptoms. The dermatologists all reviewed a selection of photographs of MC, extracted from the Cardiff and Vale University Health Board medical image library, and four of these were selected as providing a good representation of the key visual features associated with MC lesions.

Phase 2: Generating the text. Data from phase 1 were used to draft text to accompany the images. Semi-structured interviews were then conducted with a lay parent, a school nurse, and a dermatologist specialist nurse, to modify the text to ensure that it was understandable by a lay audience, without changing the meaning.

JR Olsen, MSc, PhD student; **J Gallacher**, PhD, reader in epidemiology; **NA Francis**, MD, PhD, GP and senior clinical research associate; Cochrane Institute of Primary Care and Public Health, Cardiff University, Cardiff, UK. **V Piguet**, MD, PhD, FRCP, professor of dermatology, Department of Dermatology and Wound Healing, Institute of Infection and Immunity, Cardiff University and University Hospital of Wales, Cardiff, UK.

Address for correspondence
Jonathan R Olsen, Cochrane Institute of Primary Care and Public Health, Cardiff University, Neuadd Meirionnydd, Heath Park, Cardiff CF14 4YS, Wales,.

E-mail: olsenjr@cardiff.ac.uk

Submitted: 12 February 2014; **Editor's response:** 1 March 2014; **final acceptance:** 6 March 2014

This is the full-length article (published online 28 Jul 2014) of an abridged version published in print. Cite this article as: **Br J Gen Pract 2014; DOI: 10.3399/bjgp14X680941**

How this fits in

Molluscum contagiosum is a common condition where the presentation, burden, and prognosis are not well described. It is becoming more common for parents to use online descriptions and photographs to make a diagnosis; however, none of these has been measured to compare their accuracy with diagnosis by a clinician. This article describes the development of a tool to aid parental diagnosis of molloscum contagiosum, and demonstrates that it performed well compared with GP diagnosis. The tool is available online and in paper format, and can be promoted for use by parents, used by healthcare professionals, and used for education and training, and recruitment into research studies.

Phase 3: Piloting the MCDTP. To ensure that the draft of the MCDTP was usable and acceptable, 11 members of a local parent network were asked to review the document and comment on any aspects that were unclear, and to give their views on whether they thought this tool was likely to be acceptable and useful to parents. All parents taking part in this pilot thought that it would be a useful tool, and no concerns or problems were identified. The final MCDTP is shown in Figure 1.

Validation of the diagnostic tool

Study population. A letter was sent to all general practices within Cardiff and Vale Health Board inviting them to take part in the study; 12 (of 93) practices responded. The aim was to include children aged 1 to 14 years consulting with a participating GP and currently having a skin lesion, as reported by their parent. Children were screened by practice reception staff or a researcher by asking the parent about the child's age and whether they had 'a spot, lump or bump on the skin'. Children were excluded if they currently or had previously had a diagnosis of MC. The parents of eligible children were asked to provide informed consent to participate.

Test methods. Participating parents were asked to use the MCDTP (the index test) in the practice waiting area prior to their consultation with a GP. Once they had determined whether their child had MC or not, they were asked to record this, and how confident they were in their diagnosis on a scale of 'very confident', 'confident', 'a bit confident', or 'not confident', on the form containing the MCDTP. During

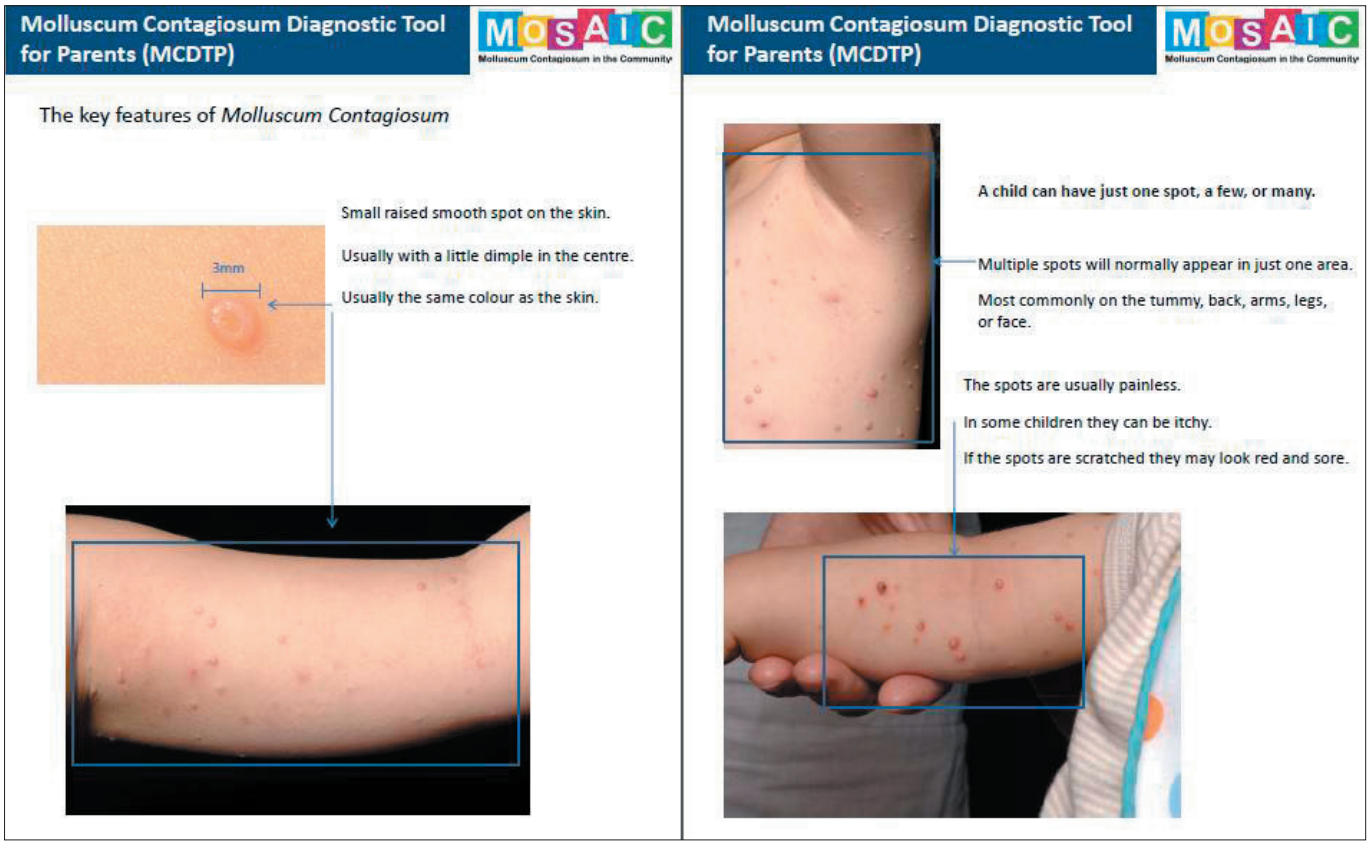

Figure 1. Molluscum Contagiosum Diagnostic Tool for Parents. ©Cardiff University 2013.

the subsequent consultation, a clinical examination of the lesion was performed by their GP (the reference test), who noted a yes/no diagnosis of MC. Index and reference tests were performed on the same day.

Photographs of 20 participants' skin lesions (10% of the total sample) were obtained. Two consultant dermatologists and one further academic GP, with an expertise in dermatology, independently reviewed these photographs to measure agreement between the MC diagnoses given by the reference standard (GP). Photographs were categorised by each independent observer as 'MC positive', 'probably MC', 'probably not MC', or 'MC negative'. For the analysis of inter-observer agreement, the categories 'probably MC' and 'probably not MC' were combined with 'MC positive' and 'MC negative', respectively.

Statistical methods. Sensitivity, specificity, positive predictive value, and negative predictive value of the MCDTP diagnosis against the reference test diagnosis were calculated. Inter-rater agreement between GP and consultant dermatologist diagnosis was also calculated. Statistical analysis was performed using Stata (version 12).

Table 1. Participant characteristics

	Sex, *n* (%)		
Age, years	**Boys**	**Girls**	**Total, *n* (%)**
1–3	36 (44)	45 (56)	81 (40)
4–6	25 (46)	29 (54)	54 (27)
7–9	19 (53)	17 (47)	36 (18)
10–14	16 (50)	16 (50)	32 (15)
Total	**96 (47)**	**107 (53)**	**203 (100)**

Table 2. Incidence of molluscum contagiosum, and sensitivity, specificity, positive predictive value, and negative predictive value for the Molluscum Contagiosum Diagnostic Tool for Parents

a) All participants regardless of confidence in diagnosis (*n* = 203)		
	%	**95% CI**
Incidence of MC	30.5 (*n* = 62)	22.9 to 35.8
Sensitivity	91.5	81.3 to 97.2
Specificity	88.2	81.8 to 93.0
Positive predictive value	76.1	64.5 to 85.4
Negative predictive value	96.2	91.4 to 98.8
b) Participants who indicated they were 'very confident' or 'confident' in their diagnosis (*n* = 158)		
	%	**95% CI**
Incidence of MC	30.4 (*n* = 48)	23.3 to 38.2
Sensitivity	95.8	85.7 to 99.5
Specificity	90.9	83.9 to 95.6
Positive predictive value	81.2	69.9 to 91.1
Negative predictive value	98.0	93.1 to 99.8

MC = molluscum contagiosum.

RESULTS

Sixty GPs across the 12 practices participated in the study. A total of 203 parents of children aged 1–14 years completed the MCDTP between January and October 2013. Participants were evenly distributed between the sexes (47% were boys, *n* = 96) and the majority were aged 1–3 years (40%, *n* = 81) (Table 1).

The incidence of MC in this population of children consulting with a GP, and identified by their parent as having a spot, lump or bump on the skin, was 30.5%. The sensitivity, specificity, positive and negative predictive values are given in Table 2. Data on confidence in their diagnosis were provided by 186 parents, and of these 85% (*n* = 158) indicated that they were either 'very confident' or 'confident' in the diagnosis of the child's skin lesion. Greater parental confidence in their diagnosis was positively associated with agreement between parental and GP diagnoses ($\chi^2 = 26.6$, degrees of freedom = 3, $P<0.005$), and the test performance characteristics improved when the analysis was restricted to this group (Table 2).

Photographs of lesions were obtained for 20 children; however, one was not of sufficient quality to be used because it was out of focus, and therefore 19 were available for the analysis. Diagnostic agreement was high, with κ statistics ranging from 0.71 between all clinicians and 0.79 between the expert GP and dermatologists (Table 3).

DISCUSSION

Summary

A diagnostic tool was developed for parental diagnosis of MC, and diagnosis by parents using the tool compared well with clinical diagnosis, with a sensitivity and specificity of 95.8% and 90.9% in the 85% of parents (*n* = 158) who indicated confidence in their diagnosis. The tool was especially good at ruling out MC (a negative predictive value of 96.2% in all patients and 98.0% in those who were confident in their diagnosis).

Strengths and limitations

The development of this tool involved a comprehensive process that involved multiple key stakeholders. In particular, the language used in the tool needed to be

Table 3. Inter-rater agreement between reference standard, GP and two dermatologists where probable and confirmed diagnosis are merged

Diagnosis of photographs (n = 19)	Agreement (%)	κ statistic	95% CI	Strength of agreement[13]
a) Agreement between GP and diagnosis made by clinician viewing image				
GP expert	94.7	0.78	0.35 to 1.0	Substantial
Dermatologist 1	89.5	0.61	0.14 to 1.0	Substantial
Dermatologist 2	84.2	0.5	0.43 to 0.95	Moderate
b) Agreement between clinicians viewing images				
	89.5	0.79	0.74 to 0.8	Substantial
c) Agreement between all clinicians (reference test and those viewing images)				
	84.2	0.71	0.56 to 0.72	Substantial

understood by a lay audience, as even the most commonly used medical terminology should be carefully explained to parents to avoid confusion.[14] A high level of agreement was found between clinicians, suggesting that the gold standard diagnosis was likely to be accurate. However, diagnosis was not able to be confirmed either histologically or by diagnosis by an expert dermatologist as this would have been expensive, burdensome to patients, and may have discouraged participation. However, high levels of agreement were found between GP diagnosis and the diagnosis made by a panel of experts, suggesting that GP diagnosis is likely to be reliable. The initial design of the MCDTP was also piloted to ensure the instructions and wording of the tool were clear and that it was acceptable to its target population.[15]

Sufficient numbers were included to allow a reasonable degree of precision around estimates. There are no data on how likely parents are to respond positively to the screening question 'Does your child have a spot, lump, or bump on the skin?' or the diagnostic accuracy in an unscreened population.

Comparison with existing literature

There are no known studies of tools for assisting parents in making a diagnosis of MC in their children. However, tools to help patients self-diagnose other skin conditions have been evaluated. The Psoriasis Screening Tool was found to have a high sensitivity and specificity of 96.4% (95% confidence intervals (CI) = 93.2 to 98.0) and 97.3% (95% CI = 94.1 to 98.9), respectively, when compared with dermatologist diagnosis.[10] A study exploring the diagnostic accuracy of self-diagnosis of a variety of skin lesions through the use of 12 lesion images and matching them to a correct diagnosis using diagnostic support software found that non-clinicians (n = 23) correctly diagnosed 96% of lesions (231 out of 240). When this was compared with medical students (n = 27) who had recently completed a 2-week dermatology attachment, and did not use diagnostic support software, their diagnostic accuracy was found to be considerably lower, 51% (160 out of 312).[11]

Using a standardised questionnaire to measure the presence of skin disease in both a health-seeking (n = 99) and non-health-seeking population (n = 98), it provided a best sensitivity and specificity of 61% and 69% compared with a dermatologist.[16] This instrument was designed to measure presence of skin disease in the population and did not identify specific conditions. Although it has a relatively low accuracy in measuring the presence of a skin condition, the authors noted that further development was required before use in a large epidemiological study.

Overall the agreement between the clinician's diagnosis and reference standard in the current study was substantial to moderate. Previous studies show agreement between a primary care physician's diagnosis of MC and a dermatologist as correct in 100% of cases;[17,18] however, these were in small studies (n = 8 and n = 3) where each rater saw the patient face to face.

The results of this study show that, although photographs alone can be effective in providing a diagnosis, in 35% of cases this was not alone sufficient to make a definitive diagnosis. It is not known how much of the observed disagreement is related to the photographs, as there may well be disagreement even when both clinicians examine the child. This is similar to other studies of much larger numbers where 20% of dermatologists did not provide a single diagnosis using only photographs, although dermatologists were able to provide a definitive diagnosis in significantly more cases during face-to-face consultations.[19] High levels of diagnostic agreement were found, which are comparable to other studies where agreement ranged between 81% and 89%.[19] Warshaw *et al*,[20] conducted a systematic review of teledermatology diagnosis agreement between a dermatologist following a face-to-face consultation, and a second using only photographs; this provided a weighted average agreement of 65.3%. In a study where a similar number of patients were assessed (n = 16), the κ coefficient of dermatologist agreement was similar to the

Funding

This research was funded by the Wales School for Primary Care Research (Reference: 504843), and as part of a postgraduate research studentship by the Cochrane Institute of Primary Care and Public Health/School of Medicine, Cardiff University (BX1150NF01).

Ethical approval

Ethical approval was obtained by NRES Committee South Central – Berkshire B (Reference: 12/SC/0455). Research governance approval was granted by Cardiff and Vale University Health Board (NISCHR-PCU Reference: 100161).

Provenance

Freely submitted; externally peer reviewed.

Competing interests

The authors have declared no competing interests.

Acknowledgements

We thank the NISCHR CRC South East Wales Research Network for support in recruitment of research sites.

Discuss this article

Contribute and read comments about this article: **bjgp.org.uk/letters**

current study data when combining all four clinicians' diagnoses (κ = 0.67),[9] Warshaw *et al*[20] showed the overall κ coefficient in a number of studies ranging from 0.65 to 0.87.

Implications for research and practice

The main aim of this study was to develop and validate a tool for use in an epidemiological study; and the data suggest that the MCDTP is suitable for this purpose. Although self-diagnosis using pictures and text is common, the validity of this has not previously been assessed. As MC is a self-limiting condition, the MCDTP could be an appropriate screening tool for use by parents in the community. It is available online (www.molluscum-info.com), and healthcare practitioners and organisations are encouraged to promote use of the site and provide a link on their websites. The site could also be used for education and training purposes, and the website and/or paper tool could be used to identify suitable patients for inclusion in studies on MC. Factors such as parent confidence in their diagnosis can be incorporated into epidemiological studies or primary care screening tools if a higher accuracy was required.

REFERENCES

1. Chen X, Anstey AV, Bugert JJ. Molluscum contagiosum virus infection. *Lancet Infect Dis* 2013; **13(10):** 877–888.
2. Hughes CM, Damon IK, Reynolds MG. Understanding US healthcare providers' practices and experiences with molluscum contagiosum. *PLoS One* 2013; **8(10):** e76948.
3. Dohil MA, Lin P, Lee J, *et al.* The epidemiology of molluscum contagiosum in children. *J Am Acad Dermatol* 2006; **54(1):** 47–54.
4. Brown J, Janniger CK, Schwartz RA, Silverberg NB. Childhood molluscum contagiosum. *Int J Dermatol* 2006; **45(2):** 93–99.
5. Olsen JR, Gallacher J, Piguet V, Francis NA. Epidemiology of molluscum contagiosum in children: a systematic review. *Fam Pract* 2014; **31(2):** 130–136.
6. Hay JR, Johns NE, Williams HC, *et al.* The global burden of skin disease in 2010: an analysis of the prevalence and impact of skin conditions. *J Invest Dermatol* 2014; **134(6):** 1527–1534.
7. Bugert JJ. Genus *Molluscipoxvirus*. In Mercer AA, Schmidt A, Weber O, (eds). *Poxviruses*. Basel: Birkhäuser, 2007. p.89–112.
8. Gould D. An overview of molluscum contagiosum: a viral skin condition. *Nurs Stand* 2008; **22(41):** 45–48.
9. Schofield JK, Fleming D, Grindlay D, Williams H. Skin conditions are the commonest new reason people present to general practitioners in England and Wales. *Br J Dermatol* 2011; **165(5):** 1044–1050.
10. Dominguez PL, Assarpour A, Kuo H, *et al.* Development and pilot-testing of a psoriasis screening tool. *Br J Dermatol* 2009; **161(4):** 778–784.
11. Aldridge RB, Glodzik D, Ballerini L, *et al.* Utility of non-rule-based visual matching as a strategy to allow novices to achieve skin lesion diagnosis. *Acta Derm Venereol* 2011; **91(3):** 279–283.
12. Brown NH, Robertson KM, Bisset YC, Rees JL. Using a structured image database, how well can novices assign skin lesion images to the correct diagnostic grouping? *J Invest Dermatol* 2009; **129(10):** 2509–2512.
13. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977: **33(1):** 159–174.
14. Lerner EB, Jehle DV, Janicke DM, Moscati RM. Medical communication: do our patients understand? *Am J Emerg Med* 2000; **18(7):** 764–766.
15. Williams HC, Strachan DP, (eds). *The challenge of dermato-epidemiology.* Boca Raton, FL: CRC Press LLC, 1997.
16. Dalgard F, Svensson A, Holm JØ, Sundby J. Self-reported skin complaints: validation of a questionnaire for population surveys. *Br J Dermatol* 2003; **149(4):** 794–800.
17. Al-Fayez H, Mukhtar S, Mohammed S. Diagnostic agreement between primary care physician and dermatologist and reason for referral to skin clinic. *Bahrain Medical Bulletin* 2004; **26(2):** 39–41.
18. Moreno G, Tran H, Chia AL, *et al.* Prospective study to assess general practitioners' dermatological diagnostic skills in a referral setting. *Australas J Dermatol* 2007; **48(2):** 77–82.
19. Gilmour E, Campbell SM, Loane MA, *et al.* Comparison of teleconsultations and face-to-face consultations: preliminary results of a United Kingdom multicentre teledermatology study. *Br J Dermatol* 1998; **139(1):** 81–87.
20. Warshaw EM, Hillman YJ, Greer NL, *et al.* Teledermatology for diagnosis and management of skin conditions: a systematic review. *J Am Acad Dermatol* 2011; **64(4):** 759–772.