## VivaScope

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Diagnostic accuracy of confocal microscopy imaging vs. punch biopsy for diagnosing and subtyping basal cell carcinoma.

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## ABSTRACT

BACKGROUND: In vivo reflectance confocal microscopy (RCM) is a promising non-invasive skin imaging technique that could facilitate early diagnosis of basal cell carcinoma (BCC) instead of routine punch biopsies. However, the clinical value and utility of RCM vs. a punch biopsy in diagnosing and subtyping BCC is unknown. OBJECTIVE: To assess diagnostic accuracy of RCM vs. punch biopsy for diagnosing and subtyping clinically suspected primary BCC. METHODS: A prospective, consecutive cohort of 100 patients with clinically suspected BCC were included at two tertiary hospitals in Amsterdam, the Netherlands, between 3 February 2015 and 2 October 2015. Patients were randomized between two test-treatment pathways: diagnosing and subtyping using RCM imaging followed by direct surgical excision (RCM one-stop-shop) or planned excision based upon the histological diagnosis and subtype of punch biopsy (standard care). The primary outcome was the agreement between the index tests (RCM vs. punch biopsy) and reference standard (excision specimen) in correctly diagnosing BCC. The secondary outcome was the agreement between the index tests and reference standard in correctly identifying the most aggressive BCC subtypes. RESULTS: Sensitivity to detect BCC was similar for RCM and punch biopsy (100% vs. 93.94%), but a punch biopsy was more specific than RCM (79% vs. 38%). RCM expert evaluation for diagnosing BCC had a sensitivity of 100% and a specificity of 75%. The agreement between RCM and excision specimen in identifying the most aggressive BCC subtype ranged from 50% to 85% vs. 77% by a punch biopsy. CONCLUSION: Reflectance confocal microscopy and punch biopsy have comparable diagnostic accuracy to diagnose and subtype BCC depending on RCM experience. Although experienced RCM users could accurately diagnose BCC at a distance, we found an important difference in subtyping BCC. Future RCM studies need to focus on diagnostic accuracy, reliability and specific criteria to improve BCC subtype differentiation. © 2017 The Authors. Journal of the European Academy of Dermatology and Venereology published by John Wiley & Sons Ltd on behalf of European Academy of Dermatology and Venereology.

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