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Development and validation of a novel topical agent for gallstone dissolution

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Introduction : Although MTBE is the only clinical topical agent for gallstone dissolution, its use is limited by its side effects mostly arising from a relatively low boiling point (55 °C).

Methods : The dissolubility of MTBE and MMP in vitro was determined by placing human gallstones in glass containers with either solvent and, then, measuring their dry weights. Their dissolubility in vivo was determined by comparing the weights of solvent-treated gallstones and control (dimethyl sulfoxide)-treated gallstones, after directly injecting each solvent into the gallbladder in hamster models with cholesterol and pigmented gallstones.

Results : In the in vitro dissolution test, MMP demonstrated statistically higher dissolubility than did MTBE for cholesterol and pigmented gallstones (88.2% vs. 65.7%, 50.8% vs. 29.0%, respectively; $P < 0.05$). In the in vivo experiments, MMP exhibited 59.0% and 54.3% dissolubility for cholesterol and pigmented gallstones, respectively, which were significantly higher than those of MTBE (50.0% and 32.0%, respectively; $P < 0.05$). The immunohistochemical stains of gallbladder specimens obtained from the MMP-treated hamsters demonstrated that MMP did not significantly increase the expression of cleaved caspase 9 or significantly decrease the expression of proliferation cell nuclear antigen.

Conclusions : This study demonstrated that MMP has better potential than does MTBE in dissolving gallstones, especially pigmented gallstones, while resulting in lesser toxicities.

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