

First clinical evaluation of a new concept for puncture-site occlusion in interventional cardiology and angioplasty.

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Abstract:

UNLABELLED: Percutaneous transluminal angioplasties of coronary and peripheral vessels are frequently used and replace open surgery in a certain percentage. Hemostasis in most of these patients is reduced or inhibited and often leads to hemorrhage from the puncture track. Due to this fact, hospitalization is not only mandatory, but also surgical revision of the puncture site is often required. We designed and produced a coaxial delivery system, which is mounted on the indwelling guide-wire after withdrawal of the instrumentation for angioplasty. The delivery system is advanced down to the outer wall of the punctured vessel and 1 cc of human two-compound fibrin glue is released. Based on our experience with laboratory and animal research, which we already presented at the 7th International Symposium on Pediatric Surgical Research in Heidelberg, May 27-28, 1994, we conducted the first trials in interventional cardiology. In 1996, a first group of 10 patients, aged 49 to 80 years, underwent sealing of the right femoral artery after diagnostic evaluation ($n = 3$) of coronary balloon dilatation ($n = 7$). In patients, the local manual compression time was less than 5 minutes and 1 patient needed 10 minutes of digital compression. In one case, bleeding continued and a compression bandage was successful, whereas in another case the local hematoma formation needed surgical revision with suture of the ruptured vessel wall.

CONCLUSION: Puncture-track sealing with locally applied fibrin glue seems to be an efficient tool to avoid bleeding after interventions of coronary and peripheral vessels. In the meantime, the device has been improved by a target system to optimize the delivery of the glue exactly at the outer wall of

the vessel.