HOW WELL DOES A HELICAL NEEDLE CATHETER DELIVER FGF-2?

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FGF-2 trials using intracoronary (IC) administration demonstrated safety and improvements in angina, but not in the primary endpoint of exercise tolerance. This outcome may be improved through local intramyocardial delivery (IMD). The BioCardia helical needle catheter (BHNIC) affixes to the beating heart wall to enable control over the time course of drug delivery. Four experiments examined the retention features of this system. Exp I: Swine (N=2) received three percutaneous BHNIC IMDs. After fluoroscopic confirmation of position, 3.3 uCi and 17 ug of 125I radiolabeled FGF-2 in a volume of 0.3cc were delivered over 30 sec and followed by 0.2cc flush of PBS. Heart and organ distribution (HaOD) was determined at 15 mins after IMD by measuring 125I-FGF-2 specific activity (TCA precipitation). Exp II: Swine (N=2) underwent Cu stenting of the LCX to induce chronic ischemia. After 3 wks, animals received IMDs and HaOD after 15 mins. Exp III: Swine (N=2) underwent Cu stenting, IMD at three wks and HaOD after 72 hrs. Exp IV: Explanted swine hearts (N=2) received IMD of 0.3cc of 125I-FGF-2 from a syringe with no flush. Counts in heart tissue were localized at the sites of IMD. Local cardiac counts per tissue mass (CPTM) were 42 to 61 times greater than for the highest CPTM sample from other organs. The non heart organ with maximum CPTM was liver at 15 min and kidney at 72 hrs. Local retention of FGF-2 after IMD with the BHNIC is greater than reported for IC delivery, and within the 4 to 40% range reported for other IMD catheters tipped with straight needles under various delivery protocols.

% FGF-2 Bound 125I Counts Delivered ±stdv

Exp	Time	Heart	Liver	Lungs	Kidney
Non Isch	15 min	18±4	42±5	7.4±0.3	5.6±2.8
Ischemic	15 min	28±19	22±9	2.5±2	3.1±2.2
Ischemic	72 hr	6.4±3	8.7±4	0.4±0.3	2.4±1.0
Explants	15 min	50±13			

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