National registration of thoraco-amniotic shunting by double-basket catheter.  
~A successful report of post-marketing surveillance~  
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Introduction
In Japan, new devices for severe fetal pleural effusion such as double-basket catheter was developed and National post-marketing surveillance has been performed as a quality control. We analyzed this national registration as all cases cohort.

Methods
- During 2011~2018, National registration were performed by website after using the catheter obligated by Ministry of Health, Labor and Welfare and The Japanese society of fetal therapy.
- We set qualified doctor to keep technical quality control. (At least 2 cases experience under experts instruction)
- Short prognosis, adverse events, risk factors were analyzed.

Results

Survival rate
Total cumulative survival rate (SR) was 80.4%(N=144), 58.7%(N=105) and 54.2%(N=97) at birth, 28 days of life, 1 year respectively. Among isolated 157 cases, SR was 79% at birth, 61% at 1 year respectively.

Fetal other complications
37% (8/22) neonates survived if severe complications such as 21trisomy, CHD, contracture syndrome, IAM, DIC etc.

Adverse events
Catheter trouble such as dislocation (14%) and obstruction (26%) happened and 1 sheath rupture, PROM 8.3%, CMS 2.2% were reported. No maternal severe complication were reported.

Conclusion
Successful national registration for newly developed devices for fetal therapy was reported. Quality control for safety in introducing TAS was established in Japan.