CRYO-ROP Study

Purpose: Multi center randomized controlled clinical trial to determine whether cryotherapy was valuable for decreasing the incidence of "unfavorable outcomes" in VLBW (1251g) babies.

Eligibility:

Patients:
- ☞VLBW (1251g)
- ☞Followed until threshold disease.
- ☞If stage 4 or more the infant was considered monocular and deemed ineligible.
- ☞Must be binocular.

Stuff:
- ☞23 centers, full retinal exam & photos.
- ☞9751 registered for study, only 291 made it to randomization.
- ☞If both eyes developed threshold one eye was randomized to receive cryo. If only one eye developed threshold only that eye was randomized. If the second eye then reached threshold it was assigned to group the first eye was not assigned to.

Patient Follow Up: ☞Initial 4 to 6 weeks. Then 2 weeks until either regression or prethreshold (zone 2, stage2, plus) then weekly.

Outcome measured: **"Unfavorable Outcome":** Anything else "favorable"
1. Posterior retinal fold.
2. RD in zone 1.
3. Retrolental mass obscuring the posterior pole.

Treatment: Cryotherapy applied to full avascular retina. Avoid the ridge.

Results:

Stats

Mean BW 800g.
Mean gestational age 26.3 weeks.
Bilateral threshold 82%
22% multiple births.
Mean postconception age 37 weeks.
17 required additional treatment.

Time	Control	Treatment
3 months	51.4%	31.1%
12 months	47.7% (Teller_56.3%)	25.7% (Teller_35%)
3.5 years	letter acuity 57.7%	46.6%
3.5 years	grating acuity 65.6%	52.4%
3.5 years	posterior pole 45.4%	26.1%

Complications:

conj hematoma	11%
Conj laceration	5.3%
Retinal hem/VH	22%
Trans CRA	0.8%
Freeze wrng pl	0.8%
Brady	9%
Cyanosis	1%

Unfavorable Outcome (Structural)

Time	Treated	Not treated
3 month	31%	51%
1 year	26%	47%
3.5 years	26%	45%
5 years	27%	45%

Unfavorable Functional Outcome (Teller or HOTV)

Time	Treated	Not treated
1 year	35%	56%
3.5 years	47%	58%
5 years	47%	62%
5 years	31.5% blind	48% blind