Early prophylactic pulmonary artery banding in isolated congenitally corrected transposition of the great arteries

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Objective: Mid-term evaluation of an aggressive surgical management of isolated congenitally corrected transposition of the great arteries (ccTGA) by pulmonary artery (PA) banding in early infancy. Methods: Between 2001 and 2009, 11 asymptomatic patients (seven neonates and four infants) underwent a dilatable, partially adjustable, homemade PA banding for ccTGA with intact ventricular septum. PA band circumference was correlated to body weight (22 mm + 1 mm kg⁻¹) and ideally adjusted to obtain flat septal geometry. Mean age at operation was 1.5 ± 1.4 months. Results: There was no hospital mortality. Mean ventilation time and intensive care unit (ICU) stay were 20 ± 9 h and 2.6 ± 1.5 days, respectively. Five patients required postoperative inotropic support. One late death occurred suddenly at 4 months; normal biventricular function and no tricuspid regurgitation were noted at last follow-up, 1 week before death. Mean follow-up was 21.5 ± 1.5 months. Conclusions: Prophylactic PA banding is safe and carries a low morbidity. At mid-term evaluation, tricuspid valve function is stabilised or improved and systemic competence of the left ventricle is maintained, thus allowing double switch if indicated.

Keywords: Congenital heart disease; Congenitally corrected transposition of the great vessels; Left ventricle retraining

1. Introduction

Double discordance, also called congenitally corrected transposition of the great arteries (ccTGA), is a cardiac arrangement in which atrio-ventricular discordance is associated with ventriculo-arterial discordance. The morphologic left ventricle (mLV) and morphologic right ventricle (mRV) support the pulmonary and systemic circulations, respectively. Conventional repair, leaving the mRV in systemic position, carries a high mortality and is associated with progressive mRV dysfunction and tricuspid regurgitation [1,2]. Severe tricuspid regurgitation that occurs is usually associated with deterioration of mRV function and functional status [3—5], similarly to the atrial switch procedure for transposition of the great arteries (TGA). Concerns about the long-term function of the morphologic right ventricle and the systemic AV valve have led to the concept of anatomic repair that restores the mLV and morphologically left AV valve to the systemic circulation [6]. To undertake anatomic repair, the mLV should have the ability to sustain a systemic pressure, similarly to patients with ccTGA with ventricular septal defect (VSD) where LV pressure is maintained at systemic levels. By contrast, for isolated ccTGA, the mLV is rapidly deconditioned due to low pulmonary artery (PA) pressure. The concept of left ventricular retraining, as initially described by Yacoub for two stage arterial switch operation [7], has been successfully applied to recondition mLV before anatomical repair in ccTGA [8—10]. In isolated ccTGA patients, we hypothesised that an early partially adjustable PA banding would preserve, rather than retrain, the mLV for systemic work, allowing later double switch if indicated. The aim of this study was to evaluate the impact of neonatal banding with special attention to mLV and mRV function.
ventricular septal geometry and tricuspid regurgitation, and to determine a future strategy for these patients.

2. Materials and methods

2.1. Patient population

From January 2001 and January 2009, 11 asymptomatic patients underwent dilatable, partially adjustable, homemaade PA banding for ccTGA with intact ventricular septum (segmental anatomy was SLL for nine patients, and IDD for two). There were six females and five males. The mean age at operation was 1.5 ± 1.4 months (median: 1 month, range: 0.5—5 months). Seven patients (64%) were aged less than 1 month. Mean weight was 4.1 ± 1.6 kg. Antenatal echocardiographic diagnosis had been made for nine patients. At diagnosis, no patient had symptoms of congestive heart failure, and all except one had been discharged home prior to readmission for elective surgery. All patients were in sinus rhythm.

Preoperative systemic (mRV) ventricular function (as assessed by echocardiography) was normal in all except two patients. One had impaired preoperative ejection fraction (less than 50%), and the other had end diastolic dilatation of the systemic ventricle (diameter indexed to normal for body surface area) with preserved systolic function. None had unbalanced ventricles.

Tricuspid regurgitation (systemic atrio-ventricular valve) was evaluated using echo-Doppler. Preoperatively, the degree of tricuspid regurgitation (TR) was non-existent to trivial in three patients (27%), mild in four (36%), moderate in three (27%) and severe in one case (9%). Varying degrees of Ebstein’s malformation of the tricuspid valve were present in three patients.

2.2. Surgical management

During the study period, a uniform surgical protocol was applied. PA banding was ideally carried out within the first month after birth. Surgery was undertaken on an elective basis after full parental consent, including information on different treatment strategies including abstention.

PA banding was performed to maintain the condition of (rather than recondition) the left ventricle. The main pulmonary trunk was exposed through a midline sternotomy approach with upper partial pericardiotomy. The PA band (3-mm width, 0.4-mm thickness) was made of a polytetrafluoroethylene (PTFE) material strip (tailored from a 0.4-mm PTFE patch) with an initial length of 22 mm + 1 mm per weight in kg. The band was applied distally rather than proximally to avoid pulmonary valve damage (future aortic valve in case of double-switch procedure). Under direct pressure monitoring (arterial and LV pressure) and transoesophageal echographic guidance, the optimal degree of constriction was achieved when the LV pressure was approximately 50% of the systemic level and so that the interventricular septum moved partially to a midline position. To get a dilatable, partially adjustable band, the optimal length of the PTFE band was secured with 6/0 polypropylene. A second 5/0 polypropylene stitch was applied on the band at optimal length plus 5 mm. This technique, routinely employed for multiple ventricular septal defects (unpublished data), allows band adjustment by balloon angioplasty to around 30 mm of length. The band itself was secured to the main pulmonary artery with one fine 6/0 polypropylene suture to prevent migration. All patients had temporary epicardial atrial and ventricular pacing wires placed and the pericardium was closed with interrupted resorbable sutures. Coronary pattern was noted on the operative report.

2.3. Data collection and statistical analysis

The health database records were reviewed in a retrospective study for the diagnosis, preoperative, operative and postoperative data and follow-up. Permission to undertake this study was obtained from Paris V University Ethics Committee. The need for individual consent was waived.

Follow-up data were obtained during a 3-month period (April 2009 and June 2009). Information was obtained for all patients.

Data were described as frequencies, medians with ranges and means with standard deviations. Continuous variables were compared using Mann–Whitney U-test and Wilcoxon test when variables were paired. Fisher’s exact test was used to determine differences when variables were expressed by dichotomous values. A p value less than 0.05 was set as the level of statistical significance. Linear regression was used to determine the relation between two continuous variables. All analyses were performed using PRISM for Macintosh version 4.0a Graphpad Software, Inc.

3. Results

3.1. Early results

3.1.1. Hospital mortality

Hospital mortality was defined as death within 30 days of operation or during the same hospital admission. There were no hospital deaths.

3.1.2. Operative data

After optimal tightening, the mean PA band length was 25.2 ± 2.4 mm (range: 22—30 mm). All band lengths were between 20 mm + 1 mm and 22 mm + 1 mm per kg weight. The observed mathematical band length/weight ratio formula was 20 mm + 1.23 mm per kg weight (Fig. 1).

3.1.3. Early morbidity

The median stay in the intensive care unit (ICU) was 2.6 ± 1.5 days (range: 1—5 days). The mean duration of ventilatory and inotropic support was 20.2 ± 18.7 h (range: 3—48 h) and 2.2 ± 1.9 days, respectively. Five patients required inotropic support (dobutamine) for depressed systolic LV function immediately after PA banding. No sternum was left open. One patient underwent re-operation for mediastinitis and two patients experienced a transient supraventricular arrhythmia.

Neonates (operated on before 1 month of age) needed less inotropic support, had shorter ventilation time and ICU stay
than infants, although there was no significant statistical difference for this small population (Table 1). Patients with preoperative moderate-to-severe TR required inotropes more frequently, had a longer ventilation time and a longer ICU stay, although not statistically significant (Table 1).

A low PA banding circumference/weight ratio was correlated with the need for inotropes, that is, tight banding led to the use of inotropic support (Fig. 2).

3.1.4. Early postoperative echocardiographic data

None of the patients had early postoperative pulmonary regurgitation, nor distortion of the pulmonary bifurcation, despite an intentionally distally positioned band. The effectiveness of the band was assessed by measurement of band velocity. An inverse correlation between velocity and PA banding circumference/weight ratio was noted (Fig. 3). In other words, there was a tendency to get higher band velocity with tight bandings ($p = 0.17$). The septum geometry was described as flat in nine patients out of 11.

3.2. Late results

3.2.1. Late survival and functional status

The mean duration of follow-up was 21.5 ± 25.8 months (range: 3 months to 7.5 years). None were lost to follow-up. There was one late sudden death, 4 months after PA banding. No necropsy was performed. At last follow-up, 8 days before death, the overall situation was considered to be satisfactory, with no clinical signs, sinus rhythm, moderate TR, no ventricular dysfunction and a band velocity of 3.15 m s$^{-1}$. At last follow-up, nine survivors were asymptomatic. One survivor was in class III and needed re-operation.

3.2.2. Late re-operations

No patient needed re-operation for band adjustment. One patient underwent late re-operation (9%) after a delay of 7.5 years. He was initially lost to follow-up but was then found to have a suprasystemic pressure in the mL V, and a band velocity of 5.8 m s$^{-1}$. On echo, there was a severely hypertrophic LV, trivial pulmonary regurgitation, but no significant TR. He initially underwent a catheter balloon angioplasty of the band but without decrease of LV pressure (being the only patient without a PTFE dilatable band). He then underwent a double-switch operation (Senning and arterial switch procedure). The postoperative course was uneventful (ventilation time: 18 h, ICU stay: 5 days). At last follow-up, a moderate aortic regurgitation and a significant decrease in LV hypertrophy were noted.

3.2.3. Late echocardiographic results

At last follow-up, the mean band velocity was significantly higher compared to early postoperative values with a

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**Table 1**

Influence of age at operation and degree of TR on early postoperative outcome.

<table>
<thead>
<tr>
<th></th>
<th>Neonates ($n=7$)</th>
<th>Infants ($n=4$)</th>
<th>$p$ value</th>
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<tbody>
<tr>
<td>Inotropic support</td>
<td>2/7</td>
<td>3/4</td>
<td>0.24$^a$</td>
</tr>
<tr>
<td>Ventilation time (h)</td>
<td>$14.9 \pm 14.8$</td>
<td>$30.7 \pm 20.6$</td>
<td>0.16$^b$</td>
</tr>
<tr>
<td>ICU stay (days)</td>
<td>$2.3 \pm 1.4$</td>
<td>$3.2 \pm 1.8$</td>
<td>0.41$^b$</td>
</tr>
<tr>
<td>No TR ($n=7$)</td>
<td></td>
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<tr>
<td>TR ($n=4$)</td>
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<tr>
<td>Inotropic support</td>
<td>2/7</td>
<td>3/4</td>
<td>0.24$^a$</td>
</tr>
<tr>
<td>Ventilation time (h)</td>
<td>$18 \pm 19.9$</td>
<td>$25.2 \pm 15.5$</td>
<td>0.16$^b$</td>
</tr>
<tr>
<td>ICU stay (days)</td>
<td>$2 \pm 1.1$</td>
<td>$3.75 \pm 1.5$</td>
<td>0.07$^b$</td>
</tr>
</tbody>
</table>

$^a$ Fisher’s exact test.

$^b$ Mann–Whitney U-test.

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Fig. 2. Influence of the PA banding circumference/weight ratio on the need for inotropic support (Mann–Whitney U-test).

Fig. 3. Linear regression between PA banding circumference/weight ratio and early band velocity.
progressive increase over time (Fig. 4). The mean band velocity increase was 0.85 m s\(^{-1}\) per year for the first 2 years (linear regression). None of the patients had impaired LV function. The echo LV mass ratio was not calculated for this cohort. Pulmonary regurgitation was absent or trivial in all cases.

3.2.4. Fate of the tricuspid valve

At last evaluation, TR was absent or trivial in six cases (55%), mild in three (27.5%) and moderate in two (17.5%). No severe TR was noted. Fig. 5 illustrates the outcome of TR during follow-up. Tricuspid regurgitation decreased in three patients, was stable in seven patients and worsened (mild-to-moderate) in one patient.

3.2.5. Magnetic resonance imaging study

Four patients were reviewed by magnetic resonance imaging (MRI) studies at 7, 8, 23 and 28 months postoperatively. The mLV mass indexed to body surface area were 36, 47, 35 and 32 g m\(^{-2}\) corresponding at same follow-up to a band velocity of 3.5, 4, 4.4 and 4.2 m s\(^{-1}\), respectively. All mLV ejection fractions ranged between 53% and 71%. No mLV diastolic dysfunction was noted. The mRV function (evaluated by end diastolic volume and end systolic volume) remained preserved but was not perfect for all patients (ejection fraction between 56% and 62%). One patient had moderate TR. Neither pulmonary regurgitation, nor pulmonary artery distortion was observed for any patient.

4. Discussion

Currently, in many centres, the optimal strategy to treat patients with ccTGA associated with a VSD seems to be to restore the mLV to systemic position, either with a double-switch procedure (atrial and arterial switch) or with an atrial switch combined with a Rastelli reconstruction [6,11,12]. For ccTGA with intact ventricular septum, there is still considerable debate regarding the optimal approach, but the good mid-term results achieved for complex ccTGA have encouraged us to adopt a strategy that would allow restoration of the mLV to systemic position, at any time, if indicated.

This strategy is also supported by the natural history of ccTGA patients [3–5], which is dominated by the high incidence of systemic mRV dysfunction and TR, leading to chronic heart failure. Late results of the Senning and Mustard procedures for TGA also enhance late RV and tricuspid dysfunction when the mRV is kept as a systemic ventricle [13,14].

These different considerations led us to adopt an aggressive approach for ccTGA in an attempt to initially stabilise the cardiac status (tricuspid and mRV function) and to offer the option of a double-switch procedure, if necessary. This strategy is based on PA banding, to maintain a conditioned mLV, and to (partially) shift the septum to the right, mimicking a ccTGA with pulmonary stenosis, known to have better outcomes than simple ccTGA [1,2]. Nevertheless, this aggressive strategy may be criticised as the natural history for ccTGA patients is extremely heterogeneous, from infant death due to mRV dysfunction, to asymptomatic patients at 40 years of age [12,15].

4.1. Timing for PA banding

In this study, the concept of early PA banding was based on the TGA (intact ventricular septum) experience. The ability of the LV to sustain systemic pressure slowly decreases after 2 weeks of age, depending upon the level of pulmonary vascular resistance [16,17]. Neonatal PA banding can probably preserve a conditioned mLV rather than enabling retraining. Moreover, during this neonatal period, increased LV afterload seems to lead more to hyperplasia than to deleterious hypertrophy [17,18]. Previous studies concerning retraining of ccTGA demonstrates that a late retraining (after 15 years of age), was an independent risk factor for retraining failure or late mLV dysfunction after double-switch procedure [8,9,19]. Antenatal diagnosis, made for nine patients (82%), facilitated this early approach (PA banding within the first month of life) to preserve a functional mLV for later systemic work. This strategy was also adopted to get an early shift of the ventricular septum towards the mRV so as to encourage improved tricuspid valve competence by normal tension of the AV valve apparatus [20,21].

For this small group of patients, the morbidity was lower in neonatal patients, although not statistically significant. Neonatal patients had fewer postoperative inotropes,
shorter ventilation time and ICU stay, which may be explained by preserved mL V function, with an immediate ability to develop pressure against the banding. These data support the strategy to band as early as possible. Now, our policy is to offer PA banding for all ccTGA diagnosed before 6 months of age. After this age, PA banding is performed if significant mRV dysfunction or TR regurgitation is noted.

4.2. PA banding technique

Distal PA banding was our technique of choice assuming that in case of later double-switch procedure, it would be better to repair mild PA distortion, rather than to have neo-aortic valve regurgitation. All except one patient had a dilatable, partially adjustable PA banding. This homemade PTFE band has been extensively used in our unit for multiple ventricular septal defects and complex congenital heart disease (unpublished data). This PTFE band offers the late option of a balloon dilatation to release the PA stenosis, by rupture of the 6/0 polypropylene suture applied at optimal length. The PTFE material does not adhere to the main PA. For ccTGA, the so-called adjustable band has been secured with a second strong suture (5/0 polypropylene), arbitrarily 2.5 mm away from the 6/0 polypropylene suture to preserve a degree of stenosis after rupture of the first stitch. The theoretical maximal circumference of the dilatable PA banding is initial optimal length plus 5 mm. This has yet to be applied for ccTGA in this series, but the situation will probably arise during follow-up.

The initial length of the band was 22 mm + 1 mm per kg weight. Finally, however, the observed length, after adjustment (pressure, echocardiogram) was 20 mm + 1.2 mm kg\(^{-1}\) for the entire cohort. The initial idea was to avoid excessive afterload, but the tolerance was good even with a more constrictive band, perhaps due to the early timing. Nevertheless, we observed that very tight banding was associated with higher morbidity (need for inotropes).

The effectiveness of PA banding has been evaluated by repeated band velocity measurement. There was a rapid band velocity increase over time of about 0.85 m s\(^{-1}\) per year for the first 2 years, starting from 2.65 m s\(^{-1}\) postoperatively, to 4.5 m s\(^{-1}\) at 2 years. If confirmed, all patients should reach a systemic pressure in the mL V in their third year of life. Fortunately, we expect to have a lower increase of the band velocity after 2 years due to the decrease of weight gain after this age. One could argue that the initial band could be a little looser but our main concern is to preserve a trained mL V rather than encouraging retraining. The relatively low early postoperative mean band velocity suggested that the PA band cannot be looser if we want to maintain a sufficient LV pressure. Nevertheless, this pressure probably does not need to reach a systemic level to avoid LV deconditioning. The ideal solution would probably be to use a fully adjustable band to avoid early deconditioning and late suprasystemic LV pressure [22]. We have no experience in this indication.

4.3. Follow-up data

During this study period, the follow-up was essentially based on echo-Doppler analysis of the heart. We recorded band velocity rather than gradient, because the Bernoulli formula cannot be applied in this situation, with the use of a large width band. The mL V mass was not calculated on echo-Doppler assuming that the mathematical model was inappropriate in this non-spherical LV. Ideally, we would have measured postero-lateral wall and the septum thickness. Specific measurements were not performed, although a general appreciation of mL V hypertrophy was obtained. The echo-Doppler was useful to describe and measure the degree of pulmonary regurgitation, PA distortion, diastolic dysfunction, and, of course, evaluate the mRV and TR. Only four patients out of 11 underwent an MRI study, and the data were particularly accurate for LV mass, systemic mRV function, quantitative analysis of the TR and pulmonary regurgitation. All four patients had preserved mL V function with an mL V mass greater than 30 g m\(^{-2}\). On this basis, we believe that the MRI study should be repeated annually for patients that tolerate such investigations without sedation. For younger patients, the frequency is yet to be determined. In this study, catheter investigations were only considered when echo suggested suprasystemic mL V pressures, moderate-to-severe mRV dysfunction or TR. This examination was considered more as a preoperative evaluation of the haemodynamic situation.

4.4. Fate of the tricuspid valve and mRV function

Unsurprisingly, the presence of a moderate-to-severe preoperative TR led to higher morbidity (need for inotropes, ventilation time and ICU stay) even if not statistically significant. Our policy was not to do concomitant systemic AV valve repair, assuming that the regurgitation is largely due to a left shift of the septum. Therefore, as others, we believe that PA banding is the best strategy to improve tricuspid valve competence (even in case of Ebstein’s-like anomalies), fighting against natural evolution [23]. During follow-up, there was a tendency for a reduction in TR (interestingly, except for the one patient who died), supporting the beneficial effect of mL V afterload. To our knowledge, the PA banding had no direct effect on mRV function but the reduction in TR can probably prevent mRV dilatation and later dysfunction.

4.5. Timing and strategy for re-intervention

The aim of this early prophylactic PA banding is not to offer a double-switch procedure for all patients but to preserve an optimal cardiac status, in other words, a functional tricuspid valve and a systemic trained LV. Nevertheless, we must keep in mind that timing and duration of training by means of PA banding may adversely affect long-term mL V function. It may cause subendocardial oedema, myocardial necrosis and fibrosis and reduced ventricular work index [24]. This can probably be avoided by frequent and repeated echo and MRI studies, allowing early adaptation of the strategy.

Our policy is to consider re-intervention only if mL V pressure becomes suprasystemic and/or severe mRV dysfunction or TR is observed. If the mL V is suprasystemic without any mRV dysfunction or severe TR, we propose partial balloon dilatation of the PA band, to achieve an ideal mL V/mRV pressure ratio of around 70%. In case of persistent
suprasystemic mL V after catheter angioplasty, we consider the double-switch procedure to be the procedure of choice. If severe mRV dysfunction and/or TR are observed, the double-switch procedure is our best option in the case of a well-prepared mL V (mL V/mRV pressure ratio >80%). If not, a redo PA banding can probably be considered.

5. Conclusions

The present study shows that PA banding can be performed in neonatal and infant patients with low morbidity. Our data demonstrated a progressive increase of the band velocity over time, right shift of the interventricular septum, TR stability or improvement and an almost preserved mL V mass over time, right shift of the interventricular septum, TR demonstrated a progressive increase of the band velocity in neonatal and infant patients with low morbidity. Our data prepared mL V (mL V/mRV pressure ratio >80%). If not, a redo PA banding can probably be considered.

References

[13] Hraska V, Duncan BW, Mayer Jr JE, Freed M, del Nido PJ, Jonas RA. An aggressive strategy might stabilise the stability or improvement and an almost preserved mL V mass over time, right shift of the interventricular septum, TR demonstrated a progressive increase of the band velocity in neonatal and infant patients with low morbidity. Our data prepared mL V (mL V/mRV pressure ratio >80%). If not, a redo PA banding can probably be considered.

Appendix A. Conference discussion

Dr M. Hazekamp (Leiden, Netherlands): Thank you, Dr Raisky, for this interesting presentation and especially for the courage that your group has to do this systematically in all patients with ccTGA and intact ventricular septum. Because many of us, including my own group, we really don’t know what is the best way to go in this group, to stay conservative or to do a banding in all patients as you do, or only band if there is tricuspid regurgitation with apical displacement of the tricuspid valve.

And while you succeeded in stabilising the septum and getting rid, in the majority of the patients, tricuspid insufficiency, still there are, of course, some comments and some questions.

As this may be overtreatment, we don’t know yet, it’s not without risk. And there is a possibility that some of those patients may have remained completely without any problems for a long period, as we know from natural history of this subset of patients. And in only one patient you did a double-switch operation.

And my question, or my main comment is, is there no fear of worsening of the left ventricular function if you have a PA band that is in place for too long and may become too tight? So wouldn’t it be better to have a standard protocol to prevent high velocities of the band and high suprasystemic pressures in the left ventricle as you may have?

You did one double-switch operation, but we don’t know the real follow-up. The left ventricle may fail later as we know from other publications. So please give me some comments on this.

Dr Raisky: Yes. This is not very comfortable to present these results because the population is very small, and the follow-up is short as well.

My main concern in this population is to reach suprasystemic morphologic left ventricular pressure quicker than expected. We have performed that kind
of banding for multiple VSDs, and usually they reach suprasystemic level quite quickly in the next 2 or 3 years.

We are also concerned about getting not only hyperplasia of the morphologic left ventricle, but hyperplasia as well, leading to impaired diastolic LV function.

We could probably avoid this by a very good follow-up of these patients, repeating echo and MRI studies. Our goal for MRI study is to check the ability of the morphologic left ventricle to be in systemic position, but at the same time not to have any diastolic function.

**Dr Hazekamp:** Yes. But you could also avoid this, maybe, I’m just speculating, by planning the double-switch operation a little bit earlier, or let’s say, standard at the weight of 10 to 15 kilos.

**Dr Raisky:** Yes. It is an option but the initial idea was not only to give the opportunity for all patients to have a double-switch procedure, but try also to stabilise their cardiac status as long as possible.

If there is no tricuspid regurgitation, and if there is no morphologic right ventricular dysfunction, then it’s fine. We don’t need to do a double-switch operation, a high risk operation, which can lead to late complications of a double switch as we have seen.

I would be very comfortable to present this series if we would have had a fully adjustable band, keeping a trained morphologic left ventricle without reaching suprasystemic pressure.

**Dr Hazekamp:** Okay. I agree, there is a lot of discussion still possible, but I’ll leave it for this.