Dedicated to the Memory of Dr. Andreas Gruentzig

(Sci-Med) - Boston Scientific

PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA)

BEFORE THE STENT ERA – „POBA" (1981 – 1997)

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PHYSIOLOGIC, „PROGRESSIVE" DILATATIONS

(Procedure Protocol – Observations and Results)

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MOTTO: "If you try to bend a live tree branch with a great velocity and force – you break it, but if you do it slowly and gently – you may weave baskets. The same principle should be applied to a live artery!"

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West Bloomfield, MI, USA – July, 2013


Old weeping willow tree and …, Chopin under a willow tree in Warsaw, Poland

Our MOTTO:

"If you try to bend a live tree branch with a great velocity and force – you break it, but if you do it slowly and gently – you may weave baskets. The same principle should be applied to a live artery!"

Old proverb:

"Rushing is good – but only, when you try to catch a flea".


Quote: Investigations in medicine made such tremendous progress, that today – practically - nobody is healthy anymore – Bertrand Russell

(1.0) Percutaneous Transluminal Coronary Angioplasty

POBA* - BEFORE THE STENT ERA (1981 – 1997)

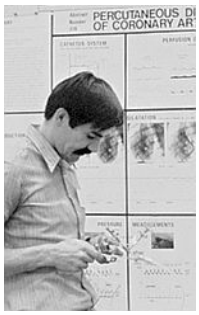
Sinai Hospital of Detroit – Waldemar J. Wajszczuk, M.D.

Independent procedure protocol, observations and results

* **POBA** – "plain old balloon angioplasty" (Not included in this report is detailed statistical analysis from the last 4 ¼ years of practice (March 1993 – June 1997, but the procedures and results were essentially similar).

Introduction

Summer 1980 – Dr. WJW – training course in Zurich, Switherland given by dr Andreas Gruenzig. Instructors: dr. Gruenzig, dr. Dotter, dr Sones, dr. Myler and dr. Stertzer. Dr. Gruenzig presented "live demonstrations" of the procedures from the catheterization laboratory. During discussion, a question was asked about the total number of the PTCA procedures performed globally and the participants' answers were written with chalk on a blackboard – they totaled already a few hundreds(!)



1980/1981 - Review of old pertinent publications – from the physiology laboratories, concerning vessel (in particular - coronary arteries) wall structure, "stretchability", resistance, elasticity, recoil etc. – it provided important information regarding optimal **duration** and **pressures** required to achieve sustained stretch and: a/ preventing: "elastic recoil" (usually occuring within the following several minutes), b/ achieving compression of the atherosclerotic plaque and c/ assuring persistent effects of stretching the "normal" (uninvolved) segments of arterial or venous walls.

February 1981 – first coronary angioplasty (PTCA) procedure at Sinai hospital (WJW)

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Initial summary of observations and results

December 1985 – summary of initial clinical observations:

a/ recurrence (**recoil**) of dilated lesions was frequently observed in the first few minutes after an apparently successful initial primary dilatation – it was likely related to an "elastic recoil" of the arterial wall;

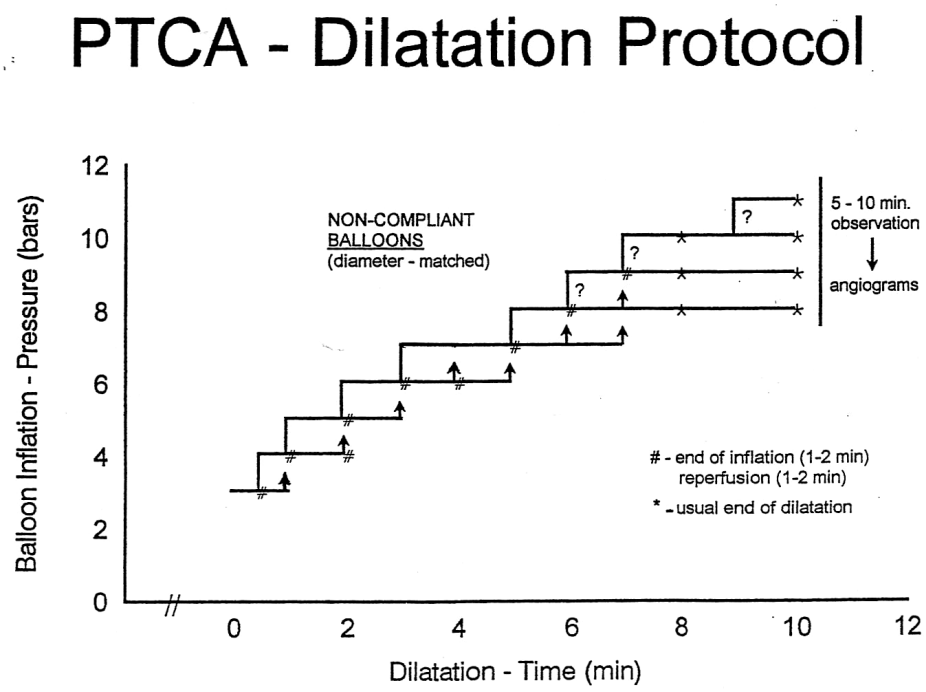
b/ suspected **dissections** of the arterial wall (contrast outside the arterial lumen) were seen less frequently after several **gradual** dilatations – of short duration with gradually increasing dilatation pressures applied **manually** by the operator – for this reason, automatic inflators were never used in subsequent procedures;

c/ patients were usually tolerating well (no anginal pain, no arrhythmia, stable arterial pressure) several short **inflations** lasting 1-2 minutes each, separated by 1-2 minute periods of **reperfusion**, for a total duration of applied pressure of 10-15 minutes;

d/ resulting from the above observations was – a development **of our own**, individual **procedure protocol** of "progressive dilatations" (early, before the arrival of "official recommendations" – which was then followed, with good results, during subsequent years;

e/ below (2.0) are summarized **results** of detailed analysis of observations and measurements from the **100 sequential procedures** performed between March and October **1985**.

Basic protocol of the procedure of coronary artery dilatations: 1-2 minute inflations, followed by 1-2 minute periods of reperfusion, repeated until observing the evidence of "**primary dilatation**"** (significant drop of the pressure gradient across the stenosis and disappearance [on the screen] of the balloon waist during inflation. After achieving the "primary dilatation", the procedure was continued with additional inflations – for at least **another 5 minutes** – with pressures increased by **1-2 atm.,** with the purpose to assure "the permanency" and "stabilization" of the stretched/compressed segment of the artery (or to "seal-off" potential small dissections). Final angiogram was performed after additional 15-20 minutes of **observation** – or longer, if there was a suspicion of dissection or otherwise any lack of stability of the dilated segment.



Basic protocol of the dilatation procedure – non-compliant balloons were used initially.

The protocol of "progressive dilatations", as described above, seems to prevent the majority of complications during the procedure, as well as subsequent restenosis, which may develop later. It was continued – with minor modifications – during the whole subsequent period of treating patients with the PTCA. See below (and a manuscript - in preparation: "Single operator's experience from ca. 2,500 POBA* dilatations during ca. 1,500 procedures performed in the late 20th century – contemporary comments").

https://www.inkling.com/read/guyton-hall-textbook-of-medical-physiology-12th/chapter-15/vascular-distensibility

Terminology:

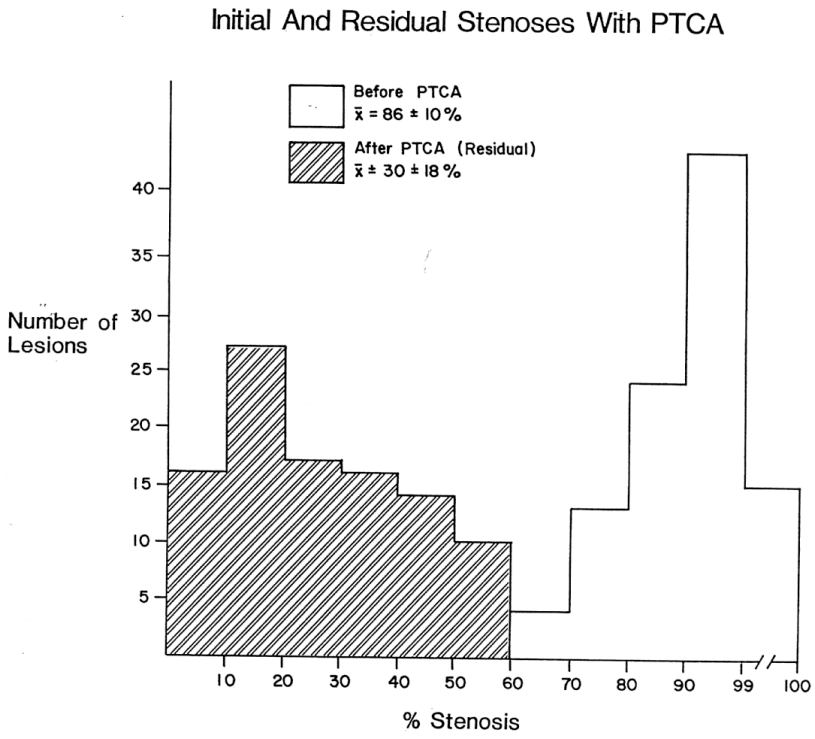
**** Explanations of the abbreviations used:**

TPG - trans-lesional pressure gradient (mmHG)" – measured across a stenosis before and after inflations.
PD – „primary dilatation" – observed on a monitor and as a drop of the pressure gradient across a stenosis → continuation of inflations is necessary! Also observe for evidence of „elastic recoil". First inflation – usually at **3-5 atm**.
EPD – „effective [persistent] dilatation" – is likely, if a"return" of stenosis (elastic recoil) is not seen after at least 10-15 min. of observation after last dilatation.
CDP – "critical/effective dilatation pressure" → primary dilatation (atherosclerotic plaque becomes compressed, fragmented, and/or normal portion of the arterial wall [if present] is stretched)
ODP – „optimal dilatation pressure" = CDP + 1-2 atm) – if continued for additional **~5 min** after apparently "adequate" dilatation – probably leads to overcoming the elastic properties (elastic recoil) of the artery?
P – applied pressure, **D** – its duration, **(P x D) –** expression of the **"stenosis resistance"**

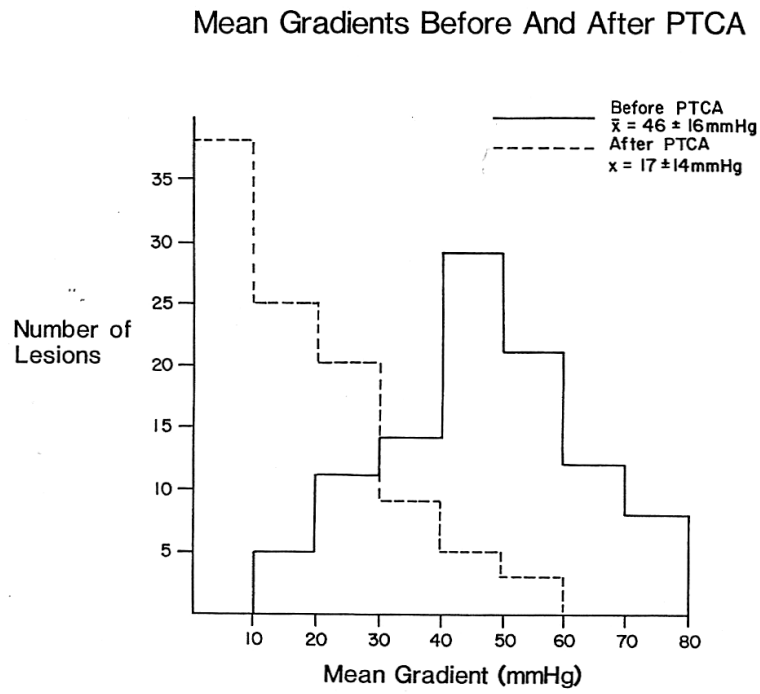
Inflation pressure: a **bar** unit (used in USA) is defined by an international unit (SI) - pascal (Pa), 1 bar ≡ 100,000 Pa.
1 bar equals: **0.987 atm**, **14.5038 psi** absolute, **29.53 inHg**, **750.06 mmHg**

Analysis of balloon inflation parameters in 100 consecutive patients

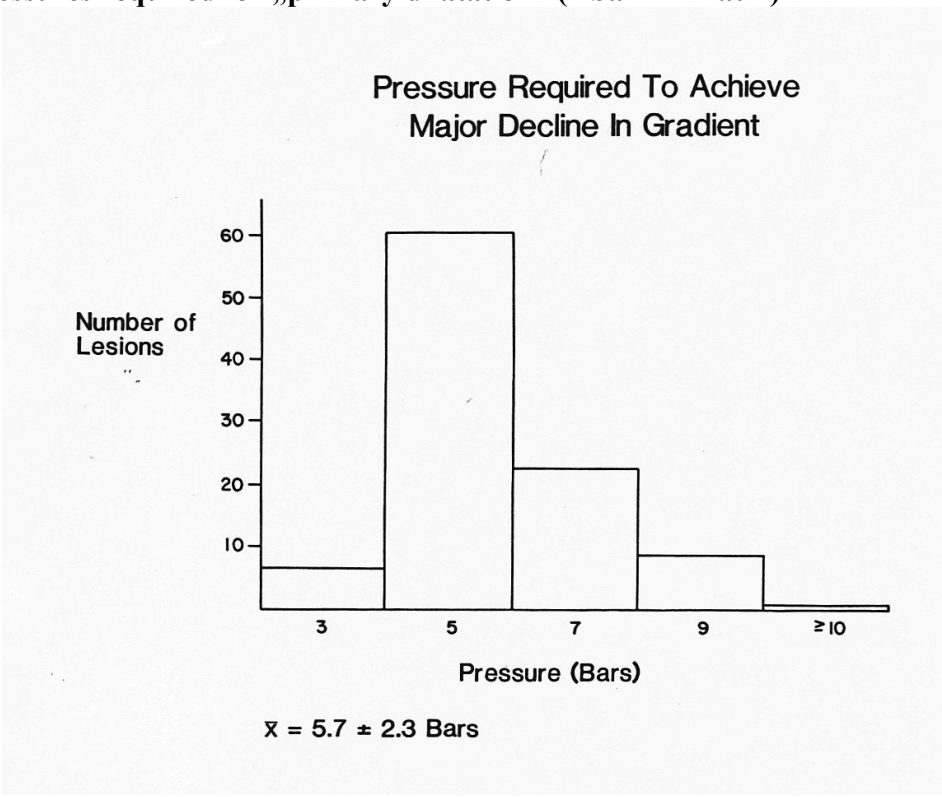
Stenosis severity (%)



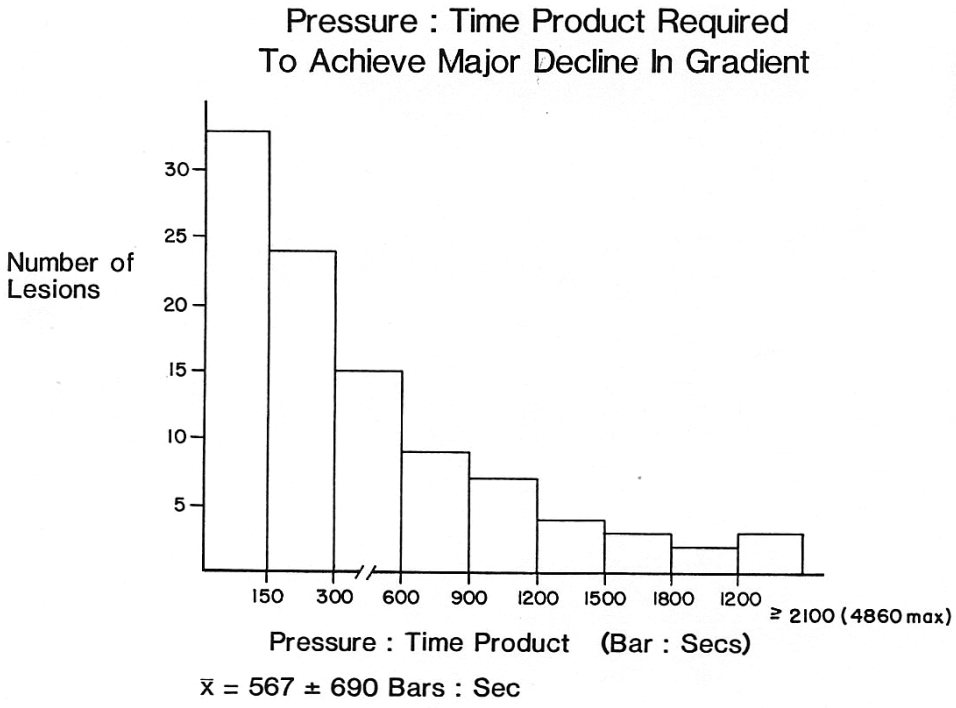
Pressure gradients across stenosis (mmHG)



Inflation pressures required for „primary dilatation" (1 bar = ~ 1 atm)

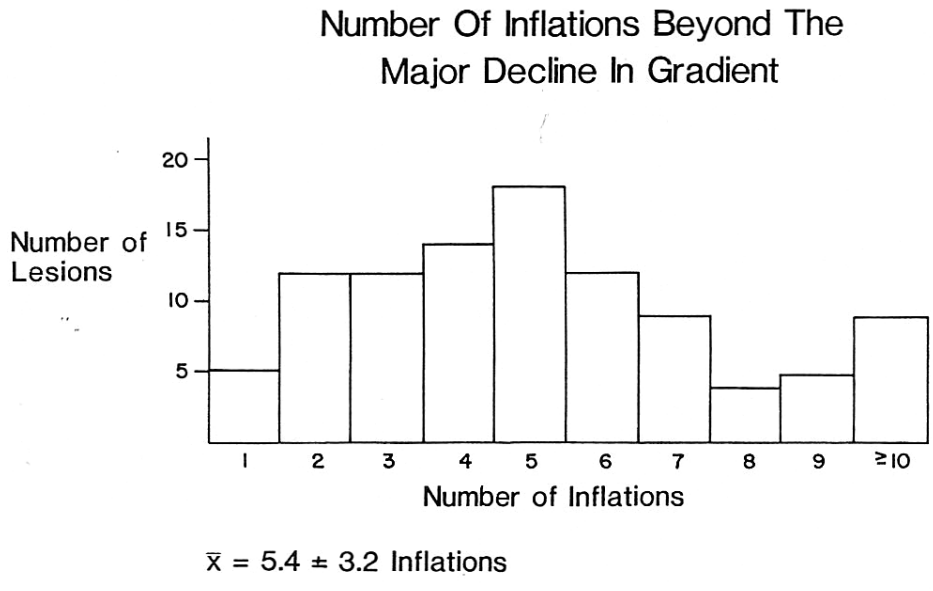


Stenosis "resistance"

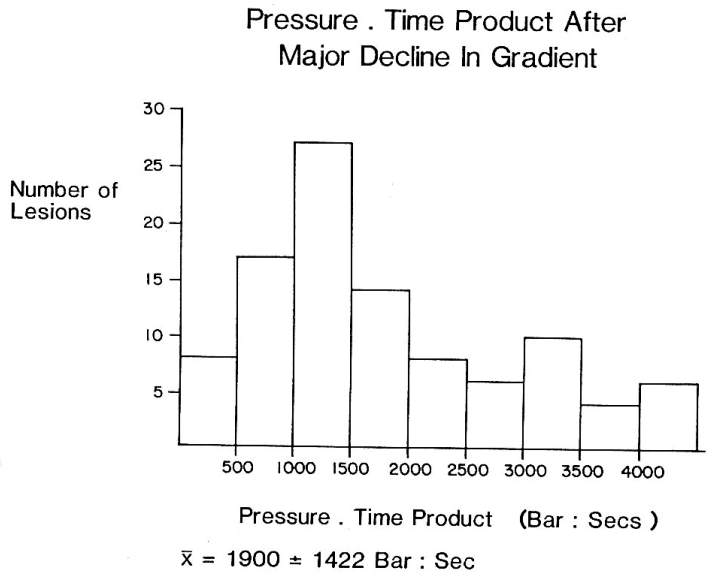


(pressure [mmHG] x time [seconds] product = an expression of the stenosis **"resistance")**

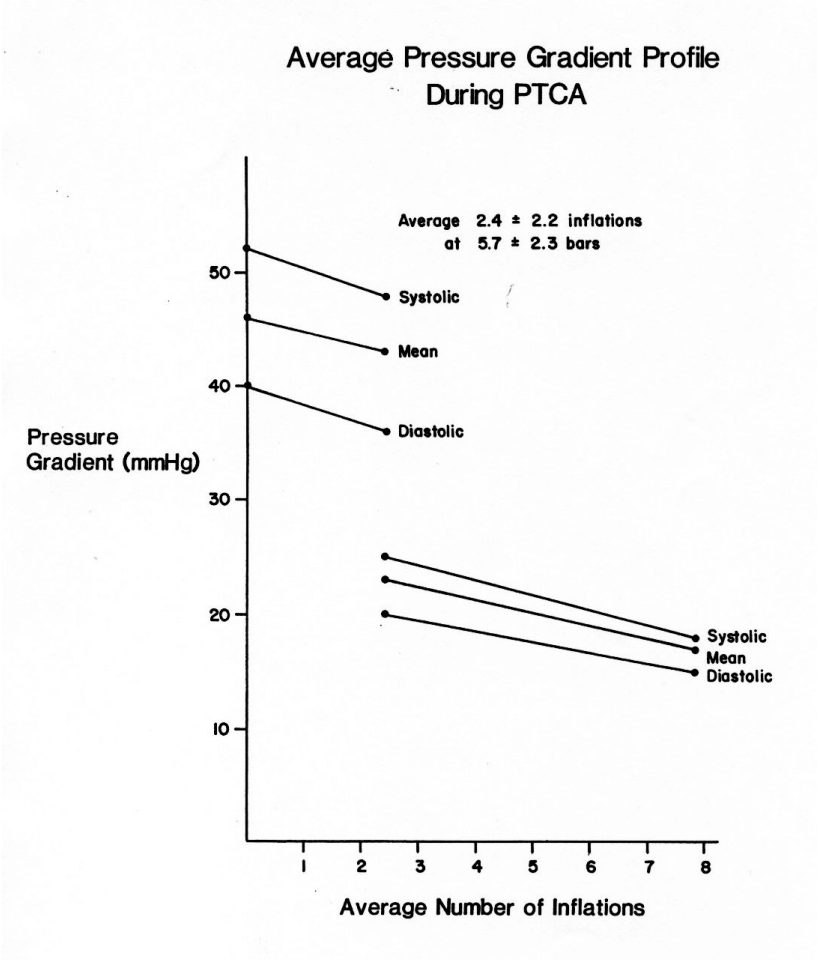
Additional inflations performed after "primary dilatation"



Additional inflations and stenosis "resistance"



Are additional inflations (beyond "primary dilatation") beneficial?



Measurements of the pressure gradients, before and after additional series of inflations (beyond the evidence of "primary dilatation"), indicate that there occurs an **additional gradient reduction** – suggesting further decrease of the stenosis "resistance" (and severity?) by additional stretch or plaque compression from continuing inflations.

(2.0) Percutaneous Transluminal Coronary Angioplasty

Procedural factors which are probably contributing to the decreased incidence of restenosis – analysis of (suspected favorable) balloon inflation parameters.

6.XII.1985 - Detroit Heart Club – (summary from October 1985)

FACTORS CONTRIBUTING TO A LOW RECURRENCE RATE OF LESIONS AFTER PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY

Waldemar J. Wajszczuk, M.D., Connie Meier, R.N., M.S.N., Nancy Piot, R.N.

A total of 275 coronary angioplasty procedures were performed at Sinai Hospital since February, 1981. One hundred and twenty-four procedures were performed this year, from January 2, 1985 through October 8, 1985. Thirty-five per cent of the procedures were in the "complex" category. Primary or "acute" success was achieved in 110 procedures (88.7%). Unsuccessful procedures included 7 in which we were unable to cross/dilate the subtotal or total occlusion (residual ischemia in the presence of previous infarction), dilatation of a bifurcation lesion using a "kissing balloon" technique was not considered adequate in one patient and he underwent coronary bypass surgery on the same day and 6 patients had acute dissection/occlusion and underwent emergency coronary bypass surgery. This constitutes a current PTCA risk of 4.8% (6/124 patients).

Among primary successes, "maintained" successful dilatation was observed in 105 patients (95.5% of those with primary success). Delayed treatment failures included two patients referred for elective CABG because of recurrence of symptoms related to clinically inadequate dilatation, 2 patients who expired 4 or 5 days after PTCA because of previous unsuccessful treatment with Streptokinase (followed by PTCA), with resultant extensive MI's, and one late LCX reclosure and death following mitral valve replacement.

The total recurrence rate among the 105 successful procedures in 1985 was 4/105 procedures (3.8%) or 4/158 lesions dilated (2.5%). Among those with at least 6 months follow-up (procedures performed prior to 5/8/85), the recurrence rate was 4/41 procedures (9.8%) or 4/54 lesions (7.4%). Among those with at least 6 months follow-up from a total series of 275 procedures and 363 lesions dilated between 1981 and 1985, the recurrence rate was 23/258 lesions or 8.5%. A number of factors, some of them unique to our procedure protocol, particularly the use of additional inflations after initial dilatation is achieved, appear to contribute to this relatively low recurrence rate.

Summary – personal statistical data (1981 – 1985):

1. 275 PTCA procedures were performed during the time period from February 1981 to October 1985.

2. 124 procedures were performed between January 2 and October 8. 1985, 35% of them in the „complex" category. Their results are summarized below;

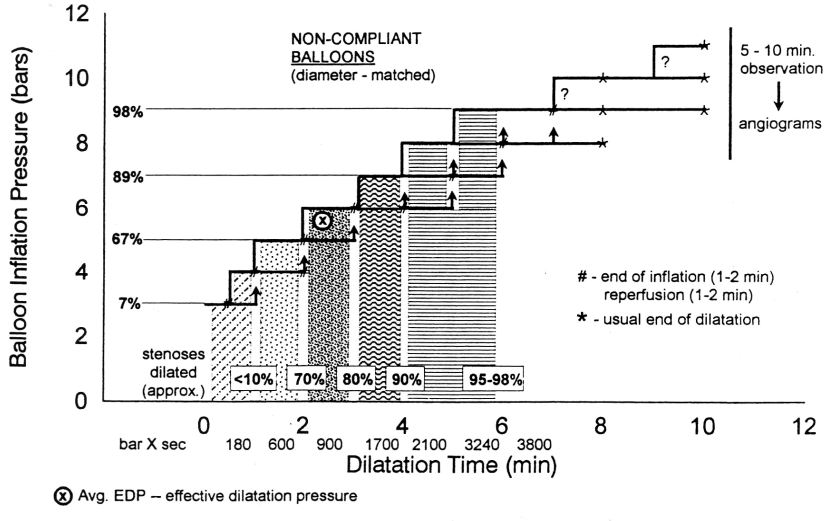
procedures were successful in 110 patients (88.7%)
severe stenosis or total occlusion could not be penetrated in 7 patients
coronary artery dissection → bypass surgery – 6/124 patients (procedure risk – 4.8%)
restenosis – observation period more than 6 months, in 1985 – 4/41 patients – (9.8%)
4/54 dilated segments – (7.4%)
restenosis – from January1981 to May 1985 – ..... - 23/258 dilatations - (8.5%)

3. information, as above, was given out to the patients.

Conclusions:

1. **Total balloon inflation time in a coronary artery should be maintained for at least 6–10 min.**
2. **Utilizing short (1-2 min) inflation periods with gradually (step-wise) increasing pressure, alternating with periods of reperfusion, appears to be safer and more effective.**
3. **It appears that the total inflation time of the balloon, and in particular the additional periods of inflation, continued and repeated after the "primary dilatation", (as seen on the monitor and based on the pressure gradient recording), have an important influence on decreasing the incidence of early "elastic recoil" and, possibly, of late restenosis.**
4. **These additional inflations, under slightly increased pressures, should probably last for at least 5 minutes (3 - 5 of one- to 2-minute inflations with short periods of reperfusion).**
5. **Observations described above are compatible with the presence in many atherosclerotic coronary stenoses of significant amount of an elastic connective tissue component, which requires, and is amenable to stretching (see above – inflation time and pressure index).**
6. **It also appears that „slow", progressive dilatation (gradual increase of the balloon pressure and diameter) is definitely less traumatic. Probably, even, if small shallow arterial wall dissections occur, they are probably less extensive and shallower. Perhaps, „self-healing" is promoted by „re-attaching" them during subsequent inflations. (See below - section about the comparison of "compliant" and „non-compliant" balloons).**
7. **Coronary angioplasty with „high pressure" balloons can be attempted in selected (high operative risk) patients with evidence of chronic, calcified plaques, but short-term and long-term results are definitely less favorable.**
8. **Balloon rupture (spontaneous or induced) is probably safe, but it depends probably to a great degree on its construction. (Contrast evacuation under very high pressures, from a small punctate tear, near the balloon seal area on the carrying catheter - forward or reverse – in its lumen, along the balloon/artery axis, was found to be entirely harmless and asymptomatic.**

PTCA - Dilatation Protocol vs.
% Stenoses Dilated -- "Primary Dilatation"



Abstract → **(slide #43) ACC 1993** – not accepted

American College of Cardiology 43rd Annual Scientific Session
ABSTRACT FORM
ABSTRACT DEADLINE: FRIDAY, SEPTEMBER 10, 1993

№ 039387

1. Abstract Category Number 0 3 (See page 3) (2 Digit)

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WALDEMAR J WAJSZCZUK MD
First Middle Initial Last/Family Degrees
SINAI HOSPITAL

PTCA Balloon Inflation Pressure and Duration Requirements for Successful Dilatations.
Waldemar J. Wajszczuk and Connie Meier, Sinai Hospital, Detroit, MI.

PTCA Balloon Inflation Pressure and Duration Requirements for Successful Dilatations.
Waldemar J. Wajszczuk and Connie Meier, Sinai Hospital, Detroit, MI.

In spite of wide use of PTCA for dilatation of coronary stenoses (S), little is known about optimal balloon inflation pressure (P) and its duration (D). A study based on radiographic observations suggested that 90% of S can be dilated with P ⩽ 8 bars. Our experience with translesional pressure gradient (TPG) measurements and incremental P dilatations for 8-10 min under standard protocol with noncompliant balloons indicated that in most of the S, "critical dilatation pressure" ("CDP") could be identified resulting in a sudden drop of TPG. In this study, responses of 100 consecutive lesions were analyzed. Mean values are presented.

Stenosis severity was reduced from 86 ± 10% to 30 ± 18 and TPG from 46 ± 16 to 17 ± 14 mmHg. "CDP" required to induce major decline of TPG (avg-20 mmHg) and assumed to overcome "resistance" of the S was 5.7 ± 2.3 bars and was reached after 2.4 ± 2.2 min. 89% of S responded to P ⩽ 7 bars, 98% to P ⩽ 9 bars, and 2% required > 10 bars. Additional inflations at P above "CDP" for D of 5.4 ± 3.2 min. further reduced the TPG by 6 ± 14 mmHg.

In conclusion: 1)TPG measurement allows precise determination of minimal effective dilatation pressure (or "CDP"), 2)in addition, it may aid in determining its optimal duration since it was observed that, 3)significant benefit is obtained from additional inflations for at least 5 minutes at pressures exceeding "CDP" (which may also help to overcome the elastic recoil and reduce restenosis rate), 4)our observations are similar to those obtained from radiographic studies, 5)new technology of Doppler guidewire TPG measurements may help in optimizing the dilatation techniques.

- Additional comments –

Abstract contains some material previously presented locally and, in addition – new analysis, illustrated in the graphic form, above - plus suggestions concerning the unification of terminology, including a new - stenosis „resistance" = P x D index.

(3.0) Percutaneous Transluminal Coronary Angioplasty

Instrumentation – improvements and new techniques

a/ Early balloon catheters – were primitive, difficult to steer – initially by shaping manually a short tapered leading segment of the component carrying catheter, later built with somewhat longer permanently attached elastic, shapeable guidewire (spring-tip);

b/ Balloon catheters - introduced and directed over a separate guide-wire – allowed measurements of pressure gradients across the stenosis;

c/ „Low-profile" balloons – allowed penetration of some of the more severe stenosis, which could not be previously crossed and dilated – both varieties: over-the-wire or with fixed spring-tip (smaller crossing profile);

d/ High-pressure balloons – allowed attempts at dilatation of chronic, resistant, calcified lesions;

e/ Other balloon techniques: multivessel coronary angioplasty, double ("kissing") balloons – for dilatation of bifurcation lesions, dilatation of long lesions with special long balloons, tortuous segments, ostial stenoses, acute and chronic total occlusions;

f/ Other techniques: Lasers, Rotablator (calcifications), Atherectomy (soft plaque excision). Balloons releasing various anti-growth substances, STENTS.

(4.0) Percutaneous Transluminal Coronary Angioplasty

Properties of balloon construction material – choosing a balloon

a/ „compliant" – elastic, stretchable
b/ „non-compliant" – non-elastic, non-stretchable
c/ „semi-compliant" – variable, intermediate properties

<u>It was considered very important.</u>

Before making a decision regarding selection and purchase of a balloon type and model, the manufacturer's representative was required to provide detailed information regarding the construction of the balloon, type of the materials used, their properties, graphic representation of the relationships between inflation pressure and balloon diameter and information regarding the balloon rupture pressure (was it rather constant and predictable?) and mode (long linear rupture, or circumscribed high pressure jet), and its typical and exact location. Was it a rather constant (repeatable) feature? Was there similarity between bench testing (no outside restriction to the balloon expansion) and reported clinical occurrences (within the confines of an artery)?

Our comparison based on analysis of a large clinical material (see below), suggested choosing for a <u>routine</u> everyday use → the "<u>compliant</u>" balloons – as less traumatic (under the procedure protocol described above), … usually of a <u>smaller</u> <u>diameter</u> (undersized) than the estimated diameter of the treated artery. Full desired size (diameter match) was accomplished by gradual step-wise increments of the inflation pressure until the desired diameter and optimal results were achieved. Details of the study are presented below.

(4.0, 5.0) Balloons – material, construction and "durability" (#35)

Material and manufacturer:

a/ "non-compliant", (N/C)
PET – Polyethylene Therephthalate (**USCI**)

b/ "semi-compliant"
PE – Polyethylene (**ACS**)
PVC – Polyvinyl Chloride (**USCI**)

c/ „compliant", (C)
POC – Polyolefin Copolymer **(SciMed**)

(4.0) Percutaneous Transluminal Coronary Angioplasty

Comparison of compliant and non-compliant balloons: (#36)

Analysis of procedures performed in 1987 – 1993 (6 years and 6 months)

1. Balloon diameter change (pressures 3 → 13 ATM): „non-compliant" - increase ~ + **8.8 %**
„compliant" – increase ~ + **32.4%**

PTCA Procedures:

2. total number, procedures - **1244**

3. individual stenoses dilated **- 2186**

4. total number of balloons used – **1913**

5. time periods compared: **1987-1989** (majority - „N/C" balloons)
1991-1993 (majority - „C" balloons)

Results of procedures: Years **1987 – 1993 (see below)** (#38)

General summary of results

1. General „complexity" of the procedures increased markedly in this time period (1987-1993);

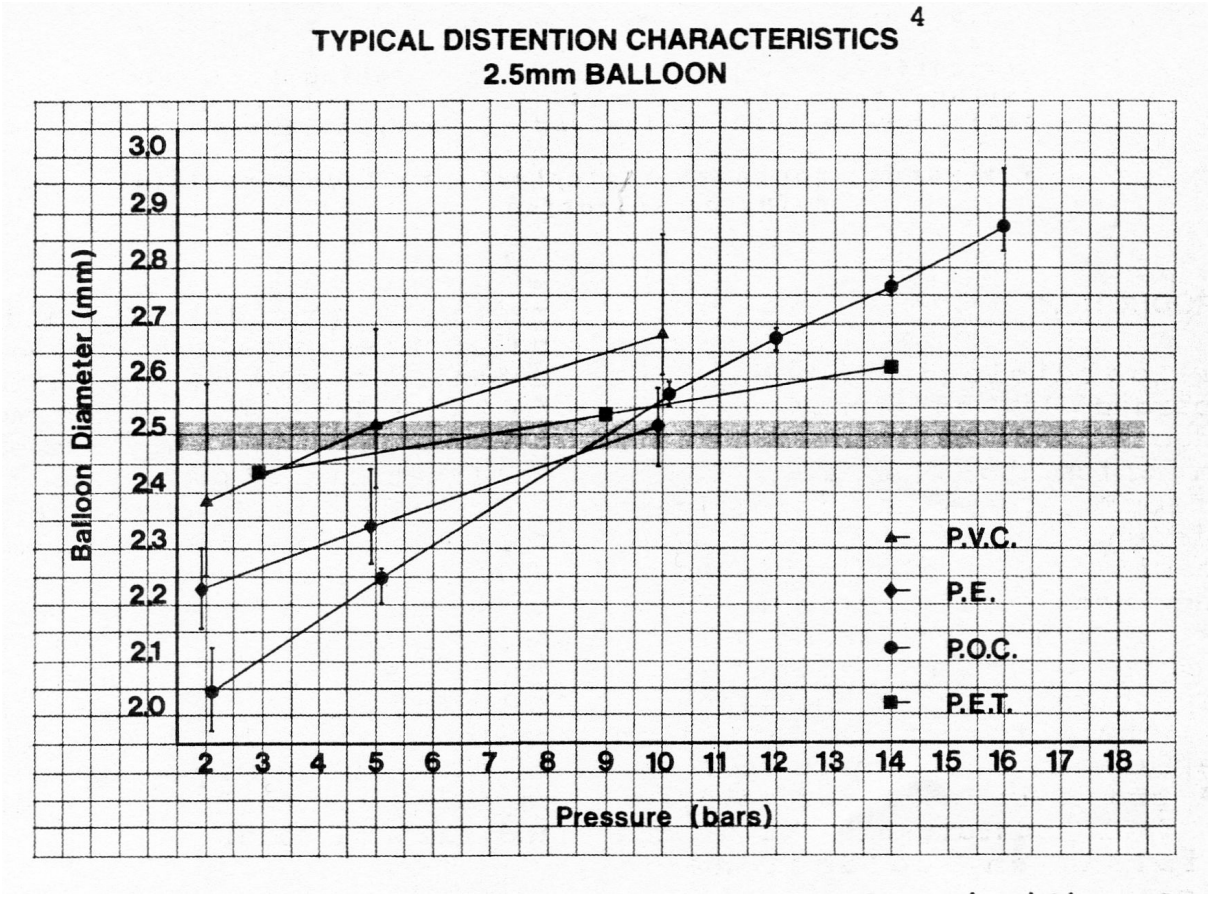
2. It appears that the usage of compliant (C) balloons is less traumatic – it decreased significantly the incidence of coronary artery dissections and therefore the need for emergency coronary bypass surgery – thus, it appears that the described method of dilatation (balloon type and gradual dilatations) is more "physiological";

3. Because the diameter of the „C" balloons increases predictably along with the increasing inflation pressures, it provided an opportunity to use the same balloon (in the same patient, if needed) in arteries of similar diameter – thus, lowering the cost of the procedure;

4. Miniaturization of the balloons allowed penetration and dilatation of more stenoses;

5. Old, chronic, calcified stenoses could be significantly improved with the use of „high pressure" balloons – in these instances „non-compliant" (N/C) balloons are preferred.

Brief overview of the technical material – examples



Comparison of the distensibility of 2.5 mm diameter balloons depending on the material used – courtesy of the SCI-MED Company. **(#40)**

F-14 balloon diameter in millimeters (Typical Values)

Atmospheres	1.5mm	2.0mm	2.5mm	3.0mm	3.5mm	4.0mm
2	1.25	1.68	2.11	2.54	2.86	3.33
3	1.32	1.77	2.22	2.67	3.04	3.51
4	1.38	1.85	2.32	2.79	3.21	3.69
5	1.45	1.93	2.41	2.90	3.37	3.86
6	1.50	2.00	2.50	3.00	3.50	4.00
7	1.56	2.08	2.60	3.11	3.63	4.17
8	1.64	2.14	2.68	3.20	3.76	4.32
9	1.70	2.19	2.75	3.28	3.85	4.42
10	1.77	2.24	2.82	3.35	3.94	4.53
11	1.83	2.29	2.89	3.34	4.03	4.66
12	1.90	2.33	2.95	3.49	4.09	4.76
13	1.96	2.36	3.02	3.56	4.15	4.86

Information concerning the F-14 - (C) balloon **(#41)**

The Ace balloon diameter in millimeters (Typical Values)

Atmospheres	2.0mm	2.5mm	3.0mm	3.5mm
3	1.68	1.98	2.53	3.08
4	1.76	2.13	2.63	3.19
5	1.83	2.26	2.74	3.30
6	1.92	2.38	2.87	3.41
7	2.00	2.50	3.00	3.50
8	2.05	2.56	3.08	3.59
9	2.09	2.61	3.16	3.66
10	2.14	2.66	3.24	3.72
11	2.19	2.71	3.31	3.77
12	2.21	2.75	3.38	3.81
13	2.26	2.79	3.44	3.85

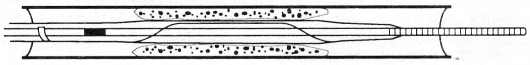


Figure 2a

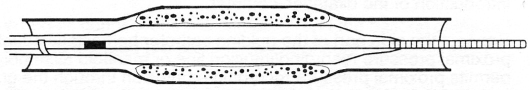


Figure 2b

Information concerning the ACE - (C) balloon **(#42)**

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Balloon Compliance for Solo Catheters

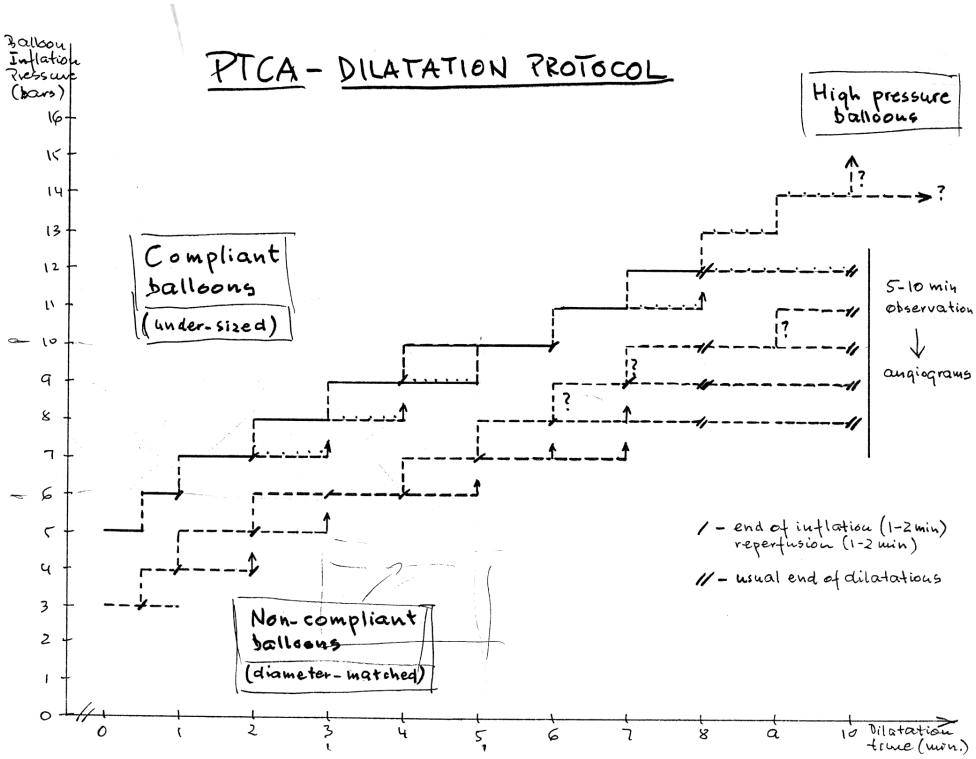
Inflation Pressure (bars)

Balloon Diameter (mm)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1.50	1.49	1.49	1.49	1.50	1.51	1.52	1.53	1.54	1.55	1.56	1.57	1.58	1.59	1.60	1.62	1.63
2.00	1.94	1.95	1.95	1.97	1.98	2.00	2.01	2.03	2.05	2.07	2.09	2.10	2.11	2.13	2.15	2.18
2.25	2.23	2.24	2.24	2.25	2.26	2.28	2.29	2.31	2.33	2.34	2.35	2.36	2.38	2.39	2.41	2.42
2.50	2.44	2.45	2.46	2.49	2.51	2.53	2.56	2.58	2.60	2.61	2.63	2.65	2.67	2.70	2.73	2.77
2.75	2.72	2.73	2.74	2.76	2.78	2.80	2.83	2.85	2.87	2.88	2.90	2.91	2.93	2.95	2.97	3.00
3.00	2.92	2.93	2.94	2.98	3.02	3.04	3.07	3.09	3.11	3.12	3.15	3.17	3.19	3.22	3.25	3.29
3.25	3.20	3.22	3.23	3.28	3.32	3.34	3.37	3.39	3.41	3.43	3.46	3.48	3.50	3.53	3.56	3.59
3.50	3.40	3.42	3.43	3.49	3.54	3.57	3.60	3.63	3.66	3.68	3.70	3.72	3.76	3.79	3.83	3.88
3.75	3.68	3.70	3.71	3.76	3.81	3.84	3.86	3.89	3.92	3.94	3.96	3.98	4.01	4.03	4.06	4.10
4.00	3.88	3.90	3.92	4.00	4.07	4.09	4.11	4.13	4.15	4.17	4.21	4.25	4.26	4.29	4.33	4.40

2.92 Number reflects measured data point
2.93 Number reflects interpolated data point

Information concerning the Solo – (N/C) balloon **(#43)**

Inflation protocols – for use during inflation of the **compliant (C)** balloons (upper tracing) – balloons used were of a <u>smaller diameter</u> than that of the artery undergoing dilatation, (balloon diameter increases along with the inflation pressure rise). Inflations were usually initiated at pressure levels, which were somewhat higher than the initial pressure, which would be used with inflations of <u>diameter-matched</u> non-compliant (**N/C**) balloons (lower tracing). **(#44)**



Comparison of the measured diameters of the (N/C) and (C) balloons based on the information provided by the manufacturers – in slides 41 – 43. (#45)

Balloon Diameter changes *
over the Range of 10 (3→13) bars (Atm.)

Balloon diameter (nominal)	Non-compliant (PET) 3 → 13 bars (mm) from to	change	%	Compliant (POC-7) 3 → 13 bars (mm) from to	change	%
1.5	1.49	1.59	(0.10)	6.7	1.31	1.79	(0.48)	32.0
2.0	1.95	2.11	(0.16)	8.0	1.74	2.39	(0.65)	32.5
2.5	2.46	2.67	(0.21)	8.4	2.17	2.99	(0.82)	32.8
3.0	2.94	3.19	(0.25)	8.3	2.61	3.58**	(0.97)	32.3
3.5	3.43	3.76	(0.33)	9.4	3.05	4.18**	(1.13)	32.3
4.0	3.92	4.25	(0.34)	8.5	—	—	—	
			mean – 8.2%				mean – 32.4%	

* according to the information ~~(tables)~~ provided by the manufactures

Analysis of the clinical material

Data from the „transitional" year 1990 was not included in this analysis (#46)

PTCA - Balloon Utilization (Sinai Hosp. - WJW)

	1987-1989	1991-1993(1/1-6/7)
Balloons (total)	781	853
Non-compliant	79.6%	4.6%
Compliant	6.9%	91.7%
Procedures	568	495
Vessels	726	863
Lesions	865	1,023
Vessels/proc.	1.28	1.74
Lesions/ proc.	1.52	2.07
Balloons/proc.	1.37	1.72
Balloons/vessel	1.08	0.99
Balloons/lesion	0.90	0.83

Comparison of years 1989, 1991 and 1993 regarding the types of balloons and their utilization, number of procedures, dilated arteries and lesions (>1/procedure) (#47)

PTCA - BALLOON UTILIZATION (SINAI HOSP. - WJW)

	1989		1991		1993 (1/1/-6/7)	
Balloons (total)	254		246		167	
Non-compliant	85.8%		6.1%		4.2%(N/C Shadow)	
Compliant	7.9%		87.0%		95.8%	
		M/Vessel		M/Vessel		M/Vessel
Procedure	187	17.1%	170	41.2%	107	40.2%
Vessels	231		274		174	
Lesions	268		318		221	
Vessels/proc.	1.24	2.18	1.61	2.44	1.63	2.56
Lesions/proc.	1.43	-	1.87	-	2.07	-
Balloons/proc.	1.36	1.78	1.45	1.91	1.56	1.98
Balloons/vessel	1.10	0.87	0.90	0.78	0.96	0.77
Balloons/lesion	0.95	-	0.77	-	0.76	-

Summary of utilization of various balloons in the individual years (#48)

	1987	1988	1989	1990	1991	1992	1993 (1/1-6/30)	
Balloons	292	235	254	256	246	440	190	1,913
Non-compliant	75.3%	78.3%	85.8%	35.9%	6.1%	3.6%	6.3%	(N/C Shadow)
"Low"-compliant	19.9%	12.3%	5.5%	4.3%	4.9	4.1%	0%	
Compliant	4.8%	8.5%	7.9%	59.8%	87.0%	92.3%	93.7%	
Trac + Micro Skinny (MVP)	14	20	4	13	4	-	-	55
ACE	-	-	12	56	55	264	166	553
DGW	-	-	4	7	4	2	0	17
F-14	-	-	-	77	145	118	7	347
P-14(Cobra)	-	-	-	-	2	3	1	6
Express	-	-	-	-	4	1	0	5
Skinny-30	-	-	-	-	-	10	0	10
Cobra-10	-	-	-	-	-	6	4	10
Shadow	-	-	-	-	-	2	0	2
N-C Shadow	-	-	-	-	-	1	12	13
	14	20	20	153	214	407	190	1,018

Comparison of balloon utilization and clinical outcomes in these two periods; (#49)

Year 1990 was „transitional" - ("N/C" → "C")

	1987	1988	1989	1990	1991	1992	1993 (1/1-6/30)
Procedures	202	179	187	170	170	218	118
Lesions (dilated)	324	273	268	277	318	484	242
Balloons	292	235	254	256	246	440	190
Non-compliant	75.3%	78.3%	85.8%	35.9%	6.1%	3.6%[a]	6.3%[a]
"Low"-compliant	19.9%	12.3%	5.5%	4.3%	4.9%	4.1%	0%
Compliant	4.8%	8.5%	7.9%	59.8%	87.0%	92.3%	93.7%
Lesions/proc.	1.60	1.53	1.43	1.63	1.87	2.22	2.05
Balloons/lesion	0.90	0.86 / 0.90	0.95	0.92	0.77	0.91 / 0.84	0.78
Occlusive Major dissections/lesion	3.7%	4.4% / 3.6%	2.6%	2.9%	0.9%	1.5% / 1.2%	1.2%
Emergency CABG/ procedure	6(3.0%)	6(3.35%) / 3.18	6(3.2%)[b]	2(1.2%)[c]	2(1.2%)[d]	1(0.5%) / 1.93	2(1.7%)[e]
Chronic occl./art (99-100%)	15(5.6%)	13(5.7%)	9(3.9%)	20(8.1%)	18(6.6%)	15(3.6%)	6(3.1%)
Balloons (-) cross/art	4.5%	2.2% / 2.7%	1.3%	1.2%	1.5%	1.0% / 1.0%	0.5%
(-) dilate/art	1.1%	1.3% / 1.4%	1.7%	0.8%	0.4%	0% / 0.13%	0%

a. "high pressure" balloons
b. two patients with acute MI, unable to dilate
c. both patients with inadequate dilatation, CABG-24-48 hrs
d. both patients inadequate dilatation, CABG same PM
e. chronic occlusion, wire perforation - one patient, balloon inflation, dissection - one patient

Abstract → **ACC 1993** (#50) – not accepted

American College of Cardiology 43rd Annual Scientific Session
ABSTRACT FORM
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Comparison of Non-Compliant and Compliant PTCA Balloons in 2186 dilated lesions - is one better or should lesion characteristics and response determine the selection.
Waldemar J. Wajszczuk, Sinai Hospital, Detroit, MI.

Comparison of Non-Compliant and Compliant PTCA Balloons in 2186 dilated lesions - is one better or should lesion characteristics and response determine the selection.
Waldemar J. Wajszczuk, Sinai Hospital, Detroit, MI.

At present, there is no standard PTCA technique and there are contradicting reports about the advantages or risks of the non-compliant (NC) or compliant (C) balloons. For 12 years, we followed a standard protocol of "physiologic" approach, i.e., incremental pressures (3-12 bars), intermittent (reperfusion) and long (8-10 min) dilatations with both types of balloons, i.e., NC-polyethylene terephthalate (PET) and C-polyolefin copolymer (POC). Results of dilatations of 2186 lesions in 1244 procedures with 1913 balloons (predominantly NC in 1987-89 and C in 1991-93) by a single operator were retrospectively analyzed.

	1987-1989	1991-93	
lesions/balloons	865/781	1044/876	
NC(PET)/C(POC)%	79.8/7.1	5.3*/91	
lesions/proc.	1.5	2.1	(↑40%)
lesions/balloon	1.1	1.2	(↑ 9%)
occl.dissec/lesion	3.6%	1.2%	(↓67%)
unable to cross/art	2.7%	1.0%	(↓63%)
unable dil/art	1.4%	0.1%	(↓93%)*

*"high pressure" balloons (HPB)

Observed trends were: 1)higher complexity of procedures. 2)C-balloons appear to be safer. They induced less visible or occlusive dissections (emergency CABG) and allowed to dilate more lesions/balloon ("pressure-adjustable" diameter)-potential cost saving, 3)miniaturization of NC and C balloons allowed crossing more stenoses, 4)virtually any lesion could be dilated with HPB (preferably NC), 5)pre-dilatation with C balloons before NC-HPB may be safer, 6)if a lesion does not respond to C balloon and (pressure-determined) diameter is reached, NC-HPB is preferred.

Does the procedure outcome depend on the balloon construction material? (#52)

	1987-1989	1991-93	
lesions/balloons	865/781	1044/876	
NC(PET)/C(POC)%	79.8/7.1	5.3*/91	
lesions/proc.	1.5	2.1	(↑40%)
lesions/balloon	1.1	1.2	(↑ 9%)
occl.dissec/lesion	3.6%	1.2%	(↓67%)
unable to cross/art	2.7%	1.0%	(↓63%)
unable dil/art	1.4%	0.1%	(↓93%)*

*"high pressure" balloons (HPB)

Summary

1.Two time periods were compared, in which a total of **2,186** dilatations were performed in the course of **1,244** procedures:

a/ **1987-1989**, (36 months), when we used primarily (in **79.8%** of dilatations) balloons constructed from non-compliant (**N/C**) materials;
b/ **1991-1993**, (30 months), when we used primarily (in **91%** of dilatations) balloons made with compliant (**C**) materials. "High-pressure" balloons, which were constructed from a non-compliant material, accounted for **5.3%**;
c/ data from **1990** was excluded from this comparison, since that was a „transition year" (from non-compliant to compliant balloons) and several other balloon models and materials were used and tested.

2. In the first time period (**N/C**)**,** when we used predominantly the non-compliant balloons, more attention was paid to select balloons with a diameter matching the estimated diameter of the treated artery, in its "normal" segments, above and below the stenosis.

3. In the second period (**C**), when we used predominantly the compliant balloons, the selected balloon diameter was usually 0.5 - 1 .0 mm smaller than the estimated diameter of the artery, thus allowing for its "growth" during serial inflations with increasing pressures. Rarely, a second larger balloon or "high pressure" non-compliant balloon had to be used.

4. Also, in the second study time period (**C**), (which was somewhat shorter):

a/ total number of coronary branches entered and stenoses dilated was higher, by **20.7%**;
b/ the number of balloons used increased less, only by **12.2%** (improved balloon utilization);
c/ mean number of stenoses dilated/procedure increased markedly, by **40%**, on the other hand, the mean number of dilated stenosis/balloon increased only slightly, by **9%**. This relatively low "balloon utilization index" could be, in part, related to a relatively higher number of procedures, in which a "high pressure" balloon (**HPB**) had to be additionally used for dilatation of "resistant" stenoses – see below.

5. Also, in the second time period (**C**), while applying the same protocol of „progressive dilatations" and while using compliant balloons, a significant decrease was noted (from **3.6%** to **1.2%**) in the incidence of coronary dissection and acute occlusions (requiring emergency coronary bypass surgery).

6. It was also noted that the incidence of failure to penetrate the stenosis/occlusion decreased from **2.7%** of the attempts in 1987-1989 to **1%** in 1991-1993. It is difficult to distinguish between the contribution of the properties (such as "slippage") of new balloon materials and their decreasing crossing profiles, especially prior to "unfolding" during the first inflation (see #42). The most significant drop was noted from 1987 to 1988, from **4.5%** to **2.2%**, (improved "crossability");

7. In the first time period (1987-1989), results of dilatations were not considered adequate in **1.4%** of the lesions, especially in those with the evidence of calcifications. After introduction of the "high pressure" (HPB) balloons in the second time period – it decreased to **0.1%** of the cases. This experience will be further discussed below,

(5.0) Percutaneous Transluminal Coronary Angioplasty

Balloon catheter construction – general information – know well your balloon! (#53):

Balloon construction - The tapered ends of small cylindrical balloons (which are manufactured separately from different materials) are „bonded" to "carrying tube/catheters". In some types of the balloons, these bonds were (still are?) reinforced with metal rings. The materials for catheter and balloon production have different characteristics – strength, flexibility, stiffness, elasticity, etc.

Reported balloon construction failures (#53) –
depend on balloon material, durability and tolerance of maximal "high" inflation pressure.

Information gathered from the literature, as well as derived from our own bench testing and clinical experience, indicate that the described instances of balloon ruptures and their complications are probably predominantly related to the balloon construction and materials used. Reports included:

a/ linear (several mm long) rupture of the side of the balloon, some with fragmentation;

b/ small puncture-type hole in the side of the balloon wall, with evacuation of its content as a high pressure jet into the side wall of the artery;

c/ localized, 2-3 mm long linear rupture in the side wall of the balloon near its tapering end with evacuation of the content into the artery, under high pressure, distally or proximally, parallelly to its long axis.

In the balloons used by us, following a rupture, we observed the contrast rapidly filling the artery distally or proximally, as described above. No adverse effects or other complications were observed in 32 cases described below and under the point (c) above (- nor in several other dozens of instances during the following years of performing the angioplasty procedures).

Balloon Strength and durability – high pressure tolerance

a/ various materials used for the construction of balloons have different physical properties – "stretchability" and tolerance of the increasing inflation pressures;

b/ as mentioned above – the manufacturers were asked to provide detailed information, also in a graphic form. In particular, we required information about the manner of the balloon rupture - linear or puncture-like, its typical location, if its location and pressure were predictable and consistent – and a mode of its content evacuation under high pressure;

c/ independently, we checked ourselves before purchasing (bench-testing in our laboratory) – the information given to us, regarding the highest tolerated inflation pressure (balloon burst/rupture) - since it has been found previously to be different for each balloon model. Small differences, which were occasionally discovered, could be most probably explained by different settings of laboratory testing – i.e. balloon rupture within, or without the outside restraining tubing.
Balloon ruptures, which were occasionally occurring during the procedures at pressures, which were lower than that determined in the laboratories at bench-testing, could be possibly explained by the presence of sharp calcifications in the arteries undergoing dilation.

(6.0) Percutaneous Transluminal Coronary Angioplasty „High Pressure Balloons" - (HPB) (#56)

Dilatation of resistant lesions with high pressure – retrospective analysis. (#57)

Summary

342 patients underwent PTCA between December 4, 1991 and February 16, 1993. 30/342 (8.8%) of them required dilatation of 32 chronic stenoses, majority of them were calcified, with application of high inflation pressures – up to 24 atm, using special balloons. Their age ranged from 48 to 80 years, mean – 70.6 years. They were divided into 2 groups:

Grup I (earlier) – included **18** patients with **18** stenoses. In all of them we used routinely at first:
a/ **standard compliant** balloons, inflated up to **16 atm** – results were unsatisfactory, then:
b/ **non-compliant „high-pressure"** balloons, inflated up to **24 atm**, with marked improvement.

Grup II (later) – **12** patients with **14** stenoses and visible calcifications. Because of these diagnostic findings, we went directly to the non-compliant **high pressure** balloons, which were gradually inflated up to maximal pressures (as required for dilatation), which ranged from **15** to **23 atm**.

1. Approximately 90% of stenoses in 342 patients could be dilated/compressed with pressures ranging up to 10 atm.
2. The remainder (most - with visible calcifications) were resistant and required adjusted dilatation protocol and utilization of special high pressure balloons;
3. Results in both groups were similar:

(Gr-I) Procedure was successful in **16/18**; shallow, stable dissection – 1, coronary bypass - 0;
follow-up (2-20 months): repeated PTCA – 2, after 4 and 5 months,
bypass surgery – 2, after 4 and 8 months;
14 patients (**78%**) doing well, w/o symptoms, after 2-20 months (mean – 10.1, median – 12).

(Gr-II) Procedure was successful in **11/12** patients; shallow, stable dissection – 3, **-->** bypass - 1;
follow-up (7-21 [35?] months): repeated PTCA – 3, after 1 day and 3 months; --> bypass – 2;
acute MI after 5 months – 1 patient, refused further treatment;
8 patients (**67%**) doing well, w/o symptoms 7-35 months after the procedure.

Conclusions

Dilatation of resistant calcified stenoses using high pressures (up to 24 atm.) and special balloons is possible, but the risk of complications is higher in this group of patients. The acute and long-term success rates are also significantly lower and recurrence rate is higher. This treatment should be probably reserved for older patients, who are at very high risk of bypass surgery.

Patients' characteristics (#60)

HIGH PRESSURE BALLOON PTCA

DEMOGRAPHIC PROFILE

29 patients

Sex : M/F	15/14
Age : mean 70.6	{range 48-88}
Previous MI	9
Acute MI	1
Previous PTCA	8
Previous CABG	5

Their coronary arteries (# 62)

HIGH PRESSURE BALLOON PTCA

ANGIOGRAPHIC VARIABLES OF STENOTIC LESIONS

Lesions		n = 32 (29 pts)
Vessel :	Lt. main	1
	LAD or branch	16
	LCX or branch	5
	Intermediate	1
	RCA	8
	Vein graft	1
//		
Eccentric		22
Augulated (>30 deg.)		11
Ostial		2
Calcifications :		
	None	4
	Mild	5
	Moderate	10
	Severe	13
Length > 2 luminal diameters		19

Summary of information regarding the HPBs used and inflation parameters (#63)

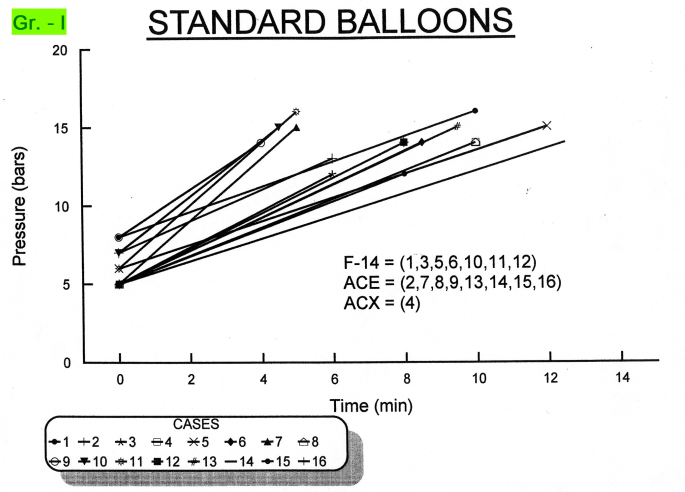
	# balloons	Max.press. (bars)	Total time (min)	Ruptured (press)
Group I (predilated)				
"Standard" balloons(POC)	18	12-16(14.2)	4-12.5(8.1)	14 (12-16)
"High pressure" balloons	19	16-24(19.9)	4-11 (6.1)	2 (18,19)
Total inflation time/stenosis		-8.5-21.1	(14.5)	
Group II				
High pressure" balloons	12	15-23(19.9)	6-13 (9.2)	2 (13,23)
Total - "High pressure" balloons	31	15-24(19.9)	4-13 (7.3)	4 (13-23)

Detailed information regarding HPB and inflations (#64)

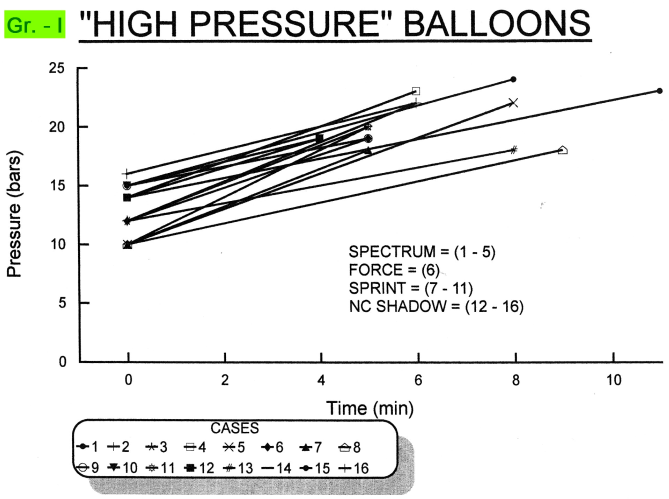
	# balloons	Max.press. (bars)	Total time (min)	Ruptured (press)
Group I (predilated)				
"Standard" balloons	18	12-16(14.2)	4-12.5(8.1)	14 (12-16)
"High pressure" balloons				
Spectrum	5	20-24(22.2)	5-8 (6.6)	-
Force	2	19 (19.0)	5.5-7 (6.2)	1 (19)
Sprint	5	18-20(18.8)	4-9 (5.6)	-
NC Shadow	7	16-23(19.3)	4-11 (6.1)	1 (18)
Total -	19	16-24(19.9)	4-11 (6.1)	2
Total inflation time/stenosis			8.5-21.1(14.5)	
Group II				
Spectrum	6	18-23(20.8)	8-13 (10.2)	-
Sprint	3	15-19(17.3)	7.5-8 (7.8)	1 (13)
NC Shadow	3*	17-23(20.7)	6-10 (8.7)	1 (23)
Total -	12	15-23(19.9)	6-13 (9.2)	2
Total - "High pressure" balloons				
Spectrum	11	18-24 (21.5)	5-13 (8.5)	-
Force	2	19 (19)	5.5-7 (6.3)	1 (19)
Sprint	8	15-20 (18.3)	4-9 (6.4)	1 (13)
NC Shadow	10*	16-23 (19.7)	4-11 (6.9)	2 (18,23)
Total -	31	15-24 (19.9)	4-13 (7.3)	4

*one balloon not included - occlusive dissection with first inflation at 10 bars

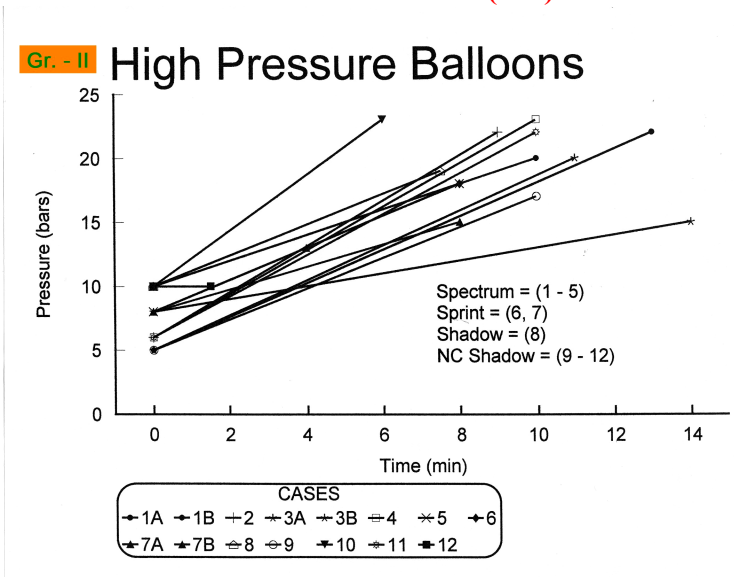
Gr.I – parameters of inflation of individual balloons (#67)



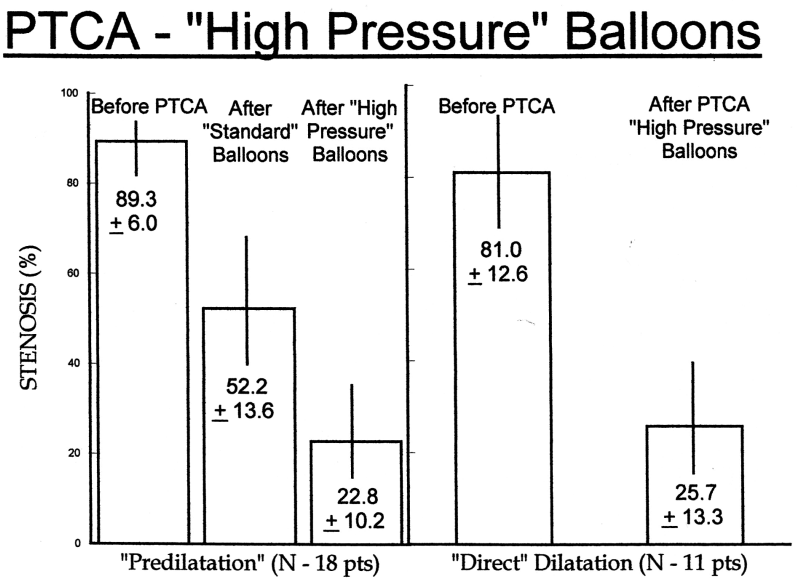
Gr.I – parameters of inflation of individual balloons (#68)



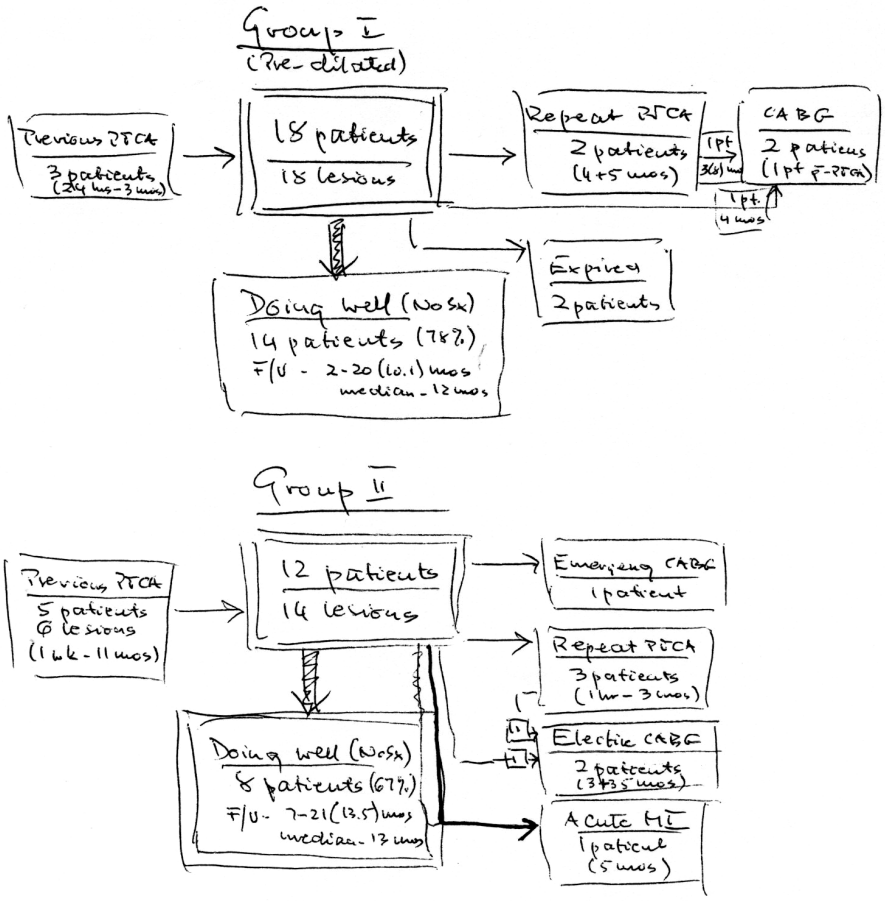
Gr.II – parameters of inflation of individual balloons (#69)



Comparison of results in both groups (I and II) (#70)



Remote results of the procedures in both groups (#71)



Abstract - (#72) (submitted to ACC?)

TREATMENT OF RESISTANT CORONARY ARTERY LESIONS USING HIGH PRESSURE BALLOON ANGIOPLASTY

Michael D. Sellers, M.D. and Waldemar J. Wajszczuk, M.D., Sinai Hospital, Detroit, Michigan.

Up to 95% of coronary artery stenoses dilate with pressures of less than 10 bars. A small percentage of lesions remain which are refractory to treatment with what can be referred to as "standard" balloon inflation pressures (that is, low pressures up to 10 bars or moderate-to-high pressures up to 16 bars). We reviewed a series of 342 consecutive patients treated for CAD with PTCA, 30 of whom (age 48-80, mean 70.6) required very high balloon inflation pressures (up to 24 bars) for a successful result. A total of 32 stenotic lesions were treated (8.8% of total reviewed). Lesions were divided into: Group A - 18 lesions (18 patients) in which compliant balloons (CB) were used initially at pressures up to 16 bars with inadequate results followed by dilation at high pressures with noncompliant balloons (NCB), and Group B - 14 lesions (12 patients) dilated only with non-compliant balloons at high pressures. Demographics of the 32 lesions included: 23 which were severely calcified, 22 which were eccentric, 11 which were angulated, 19 which were considered long (L>2D), and 2 which were ostial. Compliant balloons were inflated up to 16 bars (14 balloons ruptured), while non-compliant balloons were inflated up to 24 bars (4 balloons ruptured). No complications arose as a direct result of balloon rupture. Table below presents mean observed values:

	% stenosis			Dil. time (min)		Dil. pressure (bars)	
	pre-PTCA	post PTCA					
		(CB)	(NCB)	(CB)	(NCB)	(CB)	(NCB)
Group A	89.3	52.0	22.8	8.1	6.1	14.2	19.9
Group B	81.0	-	25.7	-	9.2	-	19.9

One patient in Group A and 3 patients in Group B had visible small dissections. One patient in Group B had dissection requiring emergent CABG. In follow up, (Group A-10.1 mos, Group B 13.5 mos), 4 patients from Group A and 3 patients from Group B required repeat revascularization procedures, either PTCA or CABG.

In conclusion, angioplasty of resistant coronary lesions with high pressures using non-compliant balloons appears to be both safe and efficacious. A small subset of lesions exist, up to 8-10% of total, which may benefit from high pressures. Pre-dilatation with compliant balloons at "standard" pressures followed by noncompliant balloons at high pressures appears to cause less arterial dissection when compared with primary application of the latter. Indications for high pressure appear to include calcified lesions, as well as long, eccentric, or angulated lesions.

Brief summary - High balloon pressure dilatations

Review of the PTCA procedures, performed in 342 patients between December 4, 1991 and February 16, 1993 revealed that 30 patients (8.8%), in whom 32 stenoses were dilated, required special high pressure balloons and dilatation pressures ranging from 16 to 24 atm. The immediate results were satisfactory, but only in 67-78% were doing well after observation periods, which ranged from 2 to 35 months. Patients with initial “pre-dilatation” with compliant balloons seemed to do slightly better. (See above for details).

(7.0) Percutaneous Transluminal Coronary Angioplasty

Balloon rupture (#75)

1.- Balloon rupture was observed in **30/342** patients (age 48-80, mean - 70.6 years), in whom **32** chronic, mostly calcified lesions were dilated from December 4, 1991 to February 16, 1993. Dilatations required high pressures, ranging up to **24 atm**. (details are described above);

2. Patients were divided into two groups - with and without initial "pre-dilatation";

- a/ in **18** patients, „standard" (18) compliant (C) balloons were used initially for "pre-dilatation". They were followed with (18) non-compliant (N/C) "high pressure" balloons, which were gradually inflated to high pressures;

- b/ in **12** patients dilatations were performed using only the high pressure, non-compliant (N/C) balloons, without the initial „pre-dilatation";

3. When balloon rupture occurred, it was associated with the sudden drop in the inflation pressure and evidence of (diluted) contrast material evacuating rapidly into the lumen of the artery – antegrade or retrograde, along its axis;

4. Ruptures occurred in these 2 groups in:

a/ (**14/18**) "standard" (C) balloons, at pressures ranging from **12** to **16 atm**
2/18 "high pressure balloons" (N/C) – inflated to **18** and **19 atm**

b/ **2/12** "high pressure balloons" (N/C) – inflated to **13** and **23 atm**

Total - **4/30** of "high pressure balloons" used, ruptured at pressures – **13, 18, 19** and **23 atm**

5. Replacement of the ruptured balloons occasionally required the removal of the whole assembly over a guidewire, including the guiding catheter, which could be accomplished without any difficulty.

6. Balloon inspection after removal revealed usually a very short (1-3 mm) localized linear rupture of its wall in its distal portion, near the ring reinforcing the balloon binding with the carrying catheter tubing, usually distally.

7. No alarming or potentially dangerous events, (as reported in the literature), were observed – such, as sudden spasm of the coronary artery, wall dissection, outside staining laterally from the lumen, or distal myocardial „blush" (from contrast material evacuated rapidly at very high pressures), no arrhythmias, angina or rupture of the artery – even at inflation pressures as high as 23 atm. **Absence of these type of complications was attributed to the balloon material, its design and construction assuring the evacuation of its contrast content along the axis of the arterial lumen, in the balloons used by us - (in models and designs, which were bench-tested earlier.)**

8. In later procedures, during subsequent years, we intentionally employed on occasion (in estimated 5–10% of the procedures) the maximal inflation pressures (while using these previously tested balloon models and being well familiar with their reliable characteristics and features), in instances of resistant lesions or to reach the maximal diameter of the balloon. No adverse effects, (immediate or remote) were observed in any of these patients.

BUT – … KNOW YOUR BALLOON!

Final Summary

A. Early results, (personal statistical data, 1981 – 1985):

1. 275 PTCA procedures were performed during the time period from February 1981 to October 1985.
2. 124 procedures were performed between January 2 and October 8. 1985, 35% of them in the „complex" category, and their details and results were analyzed;
procedures were successful in 110 patients (88.7%)
severe stenosis or total occlusion could not be penetrated in 7 patients
coronary artery dissection → bypass surgery – 6/124 patients (procedure risk – 4.8%)
restenosis – observation period more than 6 months, in 1985 – 4/41 patients – (9.8%)
4/54 dilated segments – (7.4%)
restenosis – from January1981 to May 1985 – ..... - 23/258 dilatations - (8.5%)

3. information, based on the findings, as above, was given out to the patients.

Conclusions: Slow, gradual, "progressive", and prolonged dilatations give superior results!

Dilatation Protocol – was developed on the basis of these early observations – and maintained throughout the whole period 1981- 1997

1. Total balloon inflation time in a coronary artery should be maintained for at least 6–10 min.

2. Utilizing short (1-2 min) inflation periods with gradually (step-wise) increasing pressure, alternating with periods of reperfusion, appears to be safer and more effective.

3. It appears that the total inflation time of the balloon, and in particular the additional periods of inflation, continued and repeated after the "primary dilatation", (as seen on the monitor and based on the pressure gradient recording), have an important influence on decreasing the incidence of early "elastic recoil" and, possibly, of late restenosis.

4. These additional inflations, under slightly increased pressures, should probably last for at least 5 minutes (3 - 5 of one- to-two-minute inflations with short periods of reperfusion).

5. Observations described above are compatible with the presence in many atherosclerotic coronary stenoses of asignificant amount of an elastic connective tissue component, which requires, and is amenable to stretching (see above – inflation time x pressure index).

6. It also appears that „slow", progressive dilatation (gradual increase of the balloon pressure and diameter) is definitely less traumatic. Probably, even, if small shallow arterial wall dissections occur, they are probably less extensive and shallower. Perhaps, „self-healing" is promoted by „re-attaching" them during subsequent inflations. (See below section about the comparison of "compliant" and „non-compliant" balloons).

7. Coronary angioplasty with „high pressure" balloons can be attempted in selected (high operative risk) patients with evidence of chronic, calcified plagues, but short-term and long-term results are definitely less favorable.

8. Balloon rupture (spontaneous or induced) is probably safe, but it depends probably to a great degree on its construction. Contrast evacuation under very high pressures, from a very small linear tear near the balloon seal area on the carrying catheter - forward or backward – into its lumen, along the balloon/artery axis, was found to be entirely asymptomatic and harmless.

B. Procedural and instrumentation aspects studied subsequently:

Balloon Material Selection – retrospective analysis (1987 – 1993)

1.Two time periods were compared, in which a total of **2,186** dilatations were performed in the course of **1,244** procedures:

a/ 1987-1989, (36 months), when we used primarily (in **79.8%** of dilatations) balloons constructed from non-compliant (**N/C**) materials;

b/ 1991-1993, (30 months), when we used primarily (in **91%** of dilatations) balloons made with compliant (**C**) materials. "High-pressure" balloons, which were also constructed from a non-compliant material, accounted for another **5.3%**;

c/ data from **1990** was excluded from this comparison, since that was a „transition year" (from non-compliant to compliant balloons) and several other balloon models and materials were used and tested.

	1987-1989	1991-93	
lesions/balloons	865/781	1044/876	
NC(PET)/C(POC)%	79.8/7.1	5.3*/91	
lesions/proc.	1.5	2.1	(↑40%)
lesions/balloon	1.1	1.2	(↑ 9%)
occl.dissec/lesion	3.6%	1.2%	(↓67%)
unable to cross/art	2.7%	1.0%	(↓63%)
unable dil/art	1.4%	0.1%	(↓93%)*

*"high pressure" balloons (HPB)

Comparison based on a large clinical material (see below), suggested choosing for a routine everyday use → the "compliant" balloons – as less traumatic (under the procedure protocol described above), … usually of a smaller diameter (undersized) than the estimated diameter of the treated artery. Full desired size (diameter match) was accomplished by gradual step-wise increments of the inflation pressure until the desired diameter and optimal results were achieved. Details of the study are presented above.

High Pressure Dilatations (1991 – 1993)

342 patients underwent PTCA between December 4, 1991 and February 16, 1993.
30/342 (8.8%) of them required dilatation of 32 chronic stenoses, (majority of them were calcified), with application of high inflation pressures – up to **24** atm. using special balloons. Their age ranged from 48 to 80 years, mean – 70.6 years. Some stenosis were pre-dilated with "standard" balloons. **Although dilatation of majority of those lesions was possible and the immediate results were satisfactory, but the procedure risks were higher and only 78% and 67% (with, or without pre-dilatations) were doing well after observation periods, which ranged from 2 to 35 months.** Patients with initial "pre-dilatation" with compliant balloons seemed to do slightly better. This approach should be reserved for emergencies in older patients at high risk. (See above for details).

Balloon Rupture - unintentional and induced (1991 – 1993)

Balloon rupture was observed in **30/342** patients (age 48-80, mean - 70.6 years), in whom **32** chronic, mostly calcified lesions were dilated between December 4, 1991 and February 16, 1993. Dilatations required high pressures, up to **24 atm**. (details are described above);
Balloon rupture occurred in:
a/ 14/18 "standard" compliant (C) balloons, at inflation pressures of 12-16 atm
b/ 4/40 "high pressure" non-compliant balloons, at pressures of 13-23 atm
c/ No immediate or remote ill-effects or complications were observed (See above for details)

Coronary angioplasty (PTCA) in acute MI – summary in preparation

(7/28/2014)

C. Overall clinical results (1981 – 1993) – Total experience

Table

Final summary (1981-1997)

	1981-85	1985	(36 mo.) 1987-1989	1990	(30 mo.) 1991-1993 (12/91-2/93)	(51 mo.) (3/1993-6/1997)	(est.) TOTAL
			>---------- (Total) ----------<			(Total)	
patients	275 pts.	124 pts.	(~450?); (~150?);		342 **(600?)**	(400-450?)	>2,000 pts?
stenoses	-	-	>--865 ->(2186)<-1044--<			(600?)	>3,000 sten?
balloons	-	-	>--781---(1244)--- 876--<			-	-
"complex"[a], m-vessel[b]	-	[a]35%	[b]17.1%; 29.9%;		41.2%; 40.2%	-	-
100% occluded artery			5.1%		4.6%		
balloons (total)	-	-	> --------- (1913) ---------<				
balloons (N/C)	-	-	**79.8%**		5.3%		
balloons (C)	-	-	7.1%		**91.0%**		
proc. success.	-	88.7%	-- 92.3% --		-- 97.7% --		
sten./proc.	-	-	1.5		2.1		
balloon/sten.	-	-	0.9		0.84		
dissec./stenosis →CABG	-	4.8%	-- 3.6%--		--1.2% --		
→CABG		(4.8%)	--3.18%--		--1.93%[1]		
(-) penetr./art. (%)	-	5.6%	2.7%		1.0%		
(-) dil/art. (%)	-	(5.6%)	1.4%		0.13%		
recurr. (>6 m.) - patients	-	9.8%	-		-		(est. – < 10-12%)*
- stenoses	8.5%	7.4%	-		-		
PTCA, post-previous CABG -					17.0%; 20.3%		
PTCA, post/in-acute MI -					15.9%; 20.6%		

[a] complex procedures, long strenoses, on a bend, > 1 stenosis
[b] "multi-vessel" – stenosis in > 1 coronary artery branch
[1] inadequate dilatation – 2 pts
* incomplete, ~90% follow-up, local private practice procedure referrals, verbal communications

D. Crossing difficult (sub-total) stenosis – special equipment

1/ 0.010" guidewire, 2/ Terumo wire, 3/ balloon-on-wire (0.010-0.014"), 4/ "High-pressure" balloon
http://www.terumois.com/products/guidewires/coronary.aspx?page=closer

http://pl.wikipedia.org/wiki/Angioplastyka
http://en.wikipedia.org/wiki/History_of_invasive_and_interventional_cardiology
http://en.wikipedia.org/wiki/Angioplasty
http://en.wikipedia.org/wiki/Andreas_Gruentzig
https://en.wikipedia.org/wiki/Bar_(unit)

E. Presentations, Abstracts and manuscripts

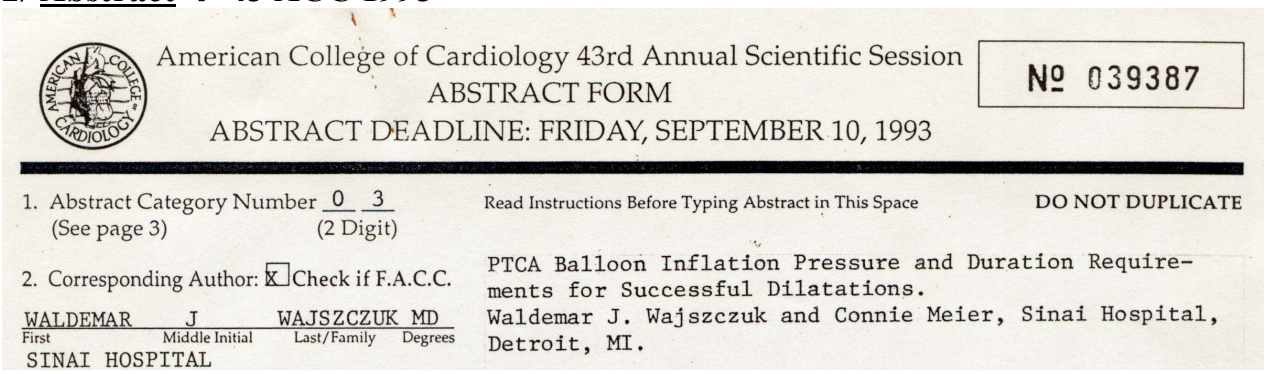
1/ Detroit Heart Club - October 1985

FACTORS CONTRIBUTING TO A LOW RECURRENCE RATE OF LESIONS AFTER PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY

Waldemar J. Wajszczuk, M.D., Connie Meier, R.N., M.S.N., Nancy Piot, R.N.

Presented on December 6, 1985

2/ Abstract → 43 ACC 1993



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WALDEMAR J WAJSZCZUK MD
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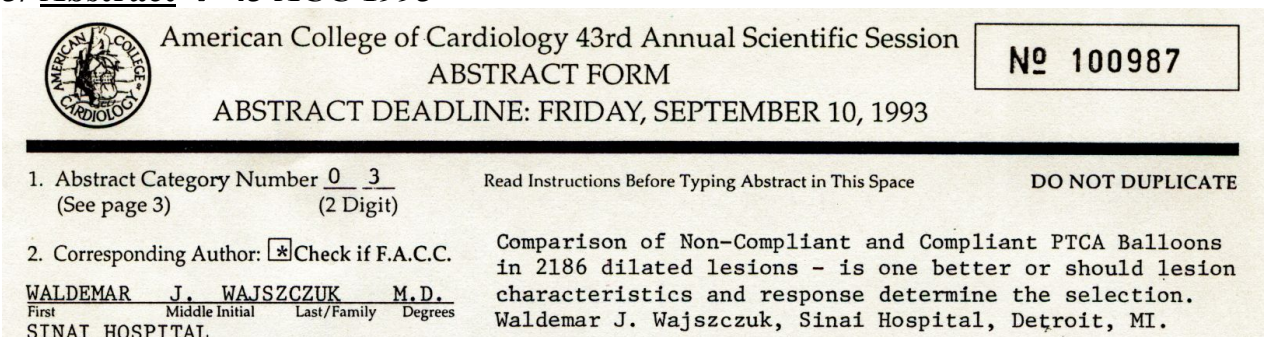
SINAI HOSPITAL

PTCA Balloon Inflation Pressure and Duration Requirements for Successful Dilatations.
Waldemar J. Wajszczuk and Connie Meier, Sinai Hospital, Detroit, MI.

3/ Abstract → 43 ACC 1993



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WALDEMAR J. WAJSZCZUK M.D.
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SINAI HOSPITAL

Comparison of Non-Compliant and Compliant PTCA Balloons in 2186 dilated lesions - is one better or should lesion characteristics and response determine the selection.
Waldemar J. Wajszczuk, Sinai Hospital, Detroit, MI.

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Unpublished manuscripts

1994

PTCA Balloon Inflation Pressure and Duration Requirements for successful dilatation – Usefulness of Pressure Gradient Measurements. – Waldemar J. Wajszczuk, MD and Connie Meier, P.A.-CMS.
Submitted for publication, Aug. 1, 1994, in CATHETERIZATION AND CARDIOVASCULAR DIAGNOSIS. Rejected – Aug. 25, 1994.

Comparison of non-compliant and compliant balloons – experience with 2,186 of dilatated stenoses – Waldemar J. Wajszczuk, MD – unpublished.

1997

„Natural History" of Coronary Angioplasty (POBA) from the single operator's perspective – from and early "craft" to current sophisticated "art" - (2013). Waldemar J. Wajszczuk, MD - unpublished

Weeping willows are beautiful!


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