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Central BP measurement and validation: the engineer's point of view

Siegfried Wassertheurer

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CURRENT OPINION

Validation of non-invasive central blood pressure devices: ARTERY Society task force consensus statement on protocol standardization

James E. Sharman[1*], Alberto P. Avolio[2], Johannes Baulmann[3], Athanase Benetos[4], Jacques Blacher[5], C. Leigh Blizzard[1], Pierre Boutouyrie[6], Chen-Huan Chen[7], Phil Chowienczyk[8], John R. Cockcroft[9], J. Kennedy Cruickshank[10], Isabel Ferreira[11], Lorenzo Ghiadoni[12], Alun Hughes[13], Piotr Jankowski[14], Stephane Laurent[6], Barry J. McDonnell[9], Carmel McEniery[15], Sandrine C. Millasseau[16], Theodoros G. Papaioannou[17], Gianfranco Parati[18,19], Jeong Bae Park[20], Athanase D. Protogerou[21], Mary J. Roman[22], Giuseppe Schillaci[23], Patrick Segers[24], George S. Stergiou[25], Hirofumi Tomiyama[26], Raymond R. Townsend[27], Luc M. Van Bortel[28], Jiguang Wang[29], Siegfried Wassertheurer[30], Thomas Weber[31], Ian B. Wilkinson[15], and Charalambos Vlachopoulos[32]

Eur Heart J. 2017 Oct 1;38(37):2805-2812.

OUTLINE

- Method issues
- Accuracy
- Sample size
- Intervention
- Calibration and mean pressure

REFERENCE STANDARD

(3) *Recommendations*. The reference standard against which device accuracy of central BP estimation is gauged should be intra-arterial catheter in the ascending aorta [expanded details within section entitled '*Invasive (intra-arterial) central BP reference standard*']. The calibra-

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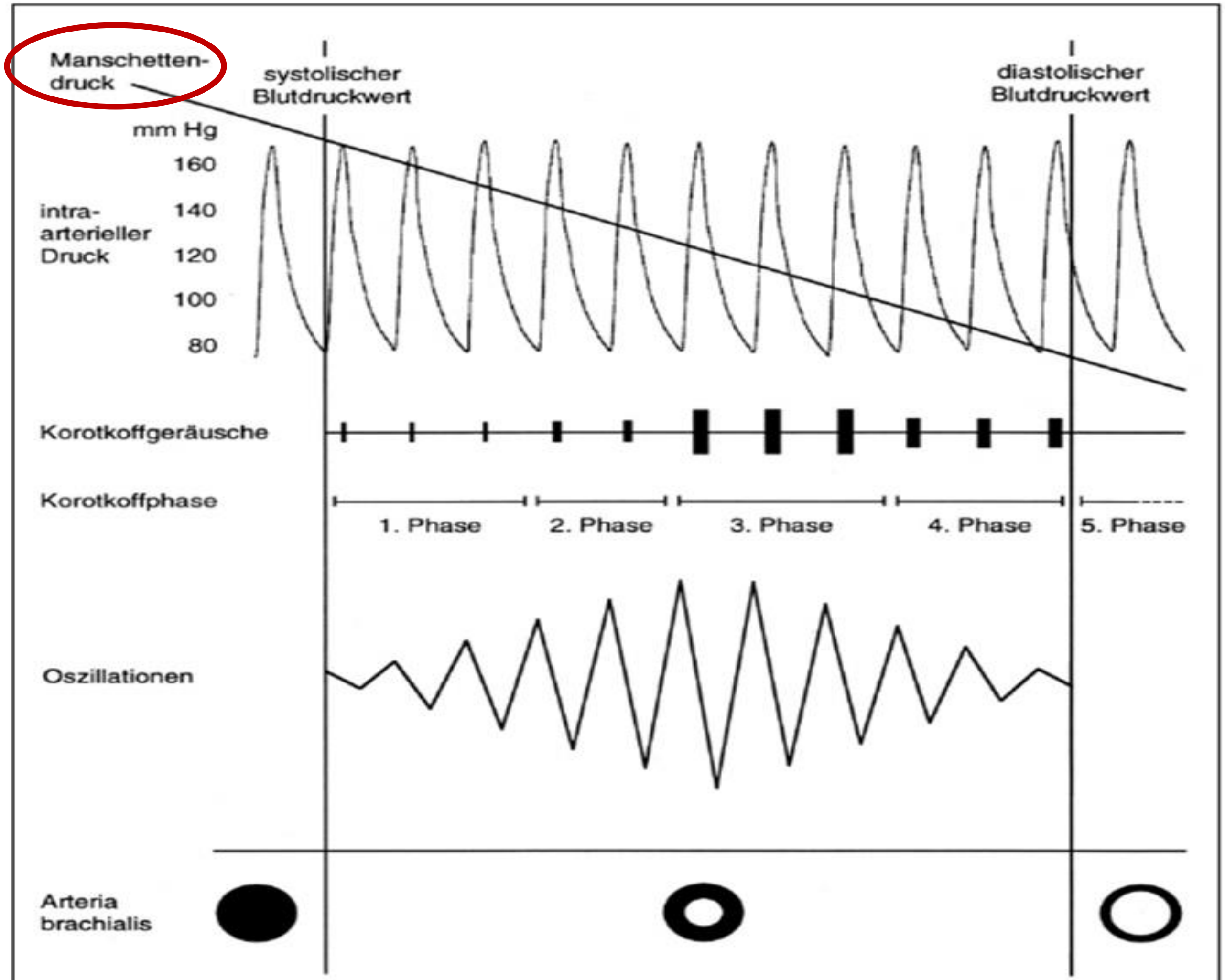
METHODS COCKTAIL



Eckert S, Journal für Hypertonie 2006; 10 (3), 7-13

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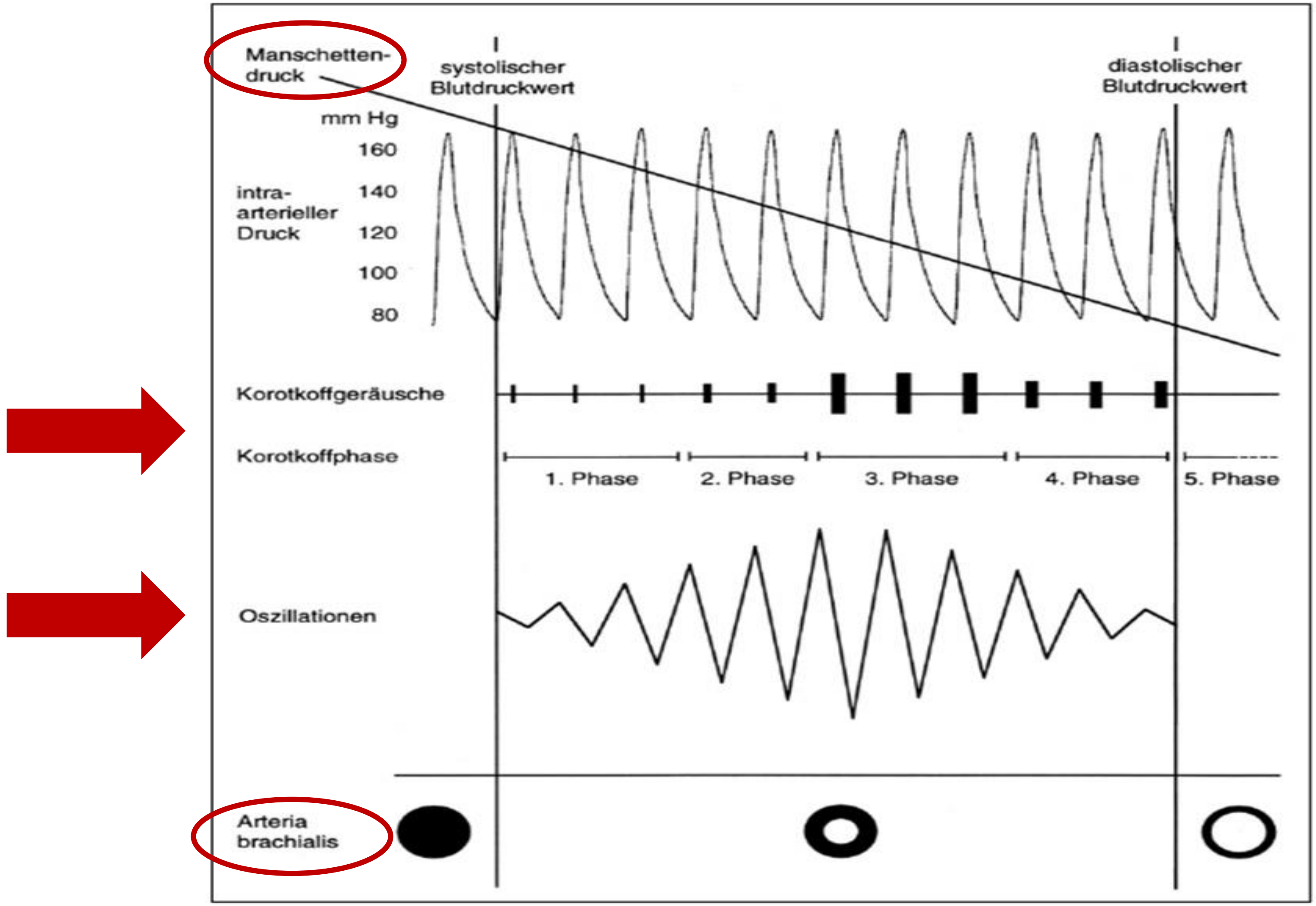

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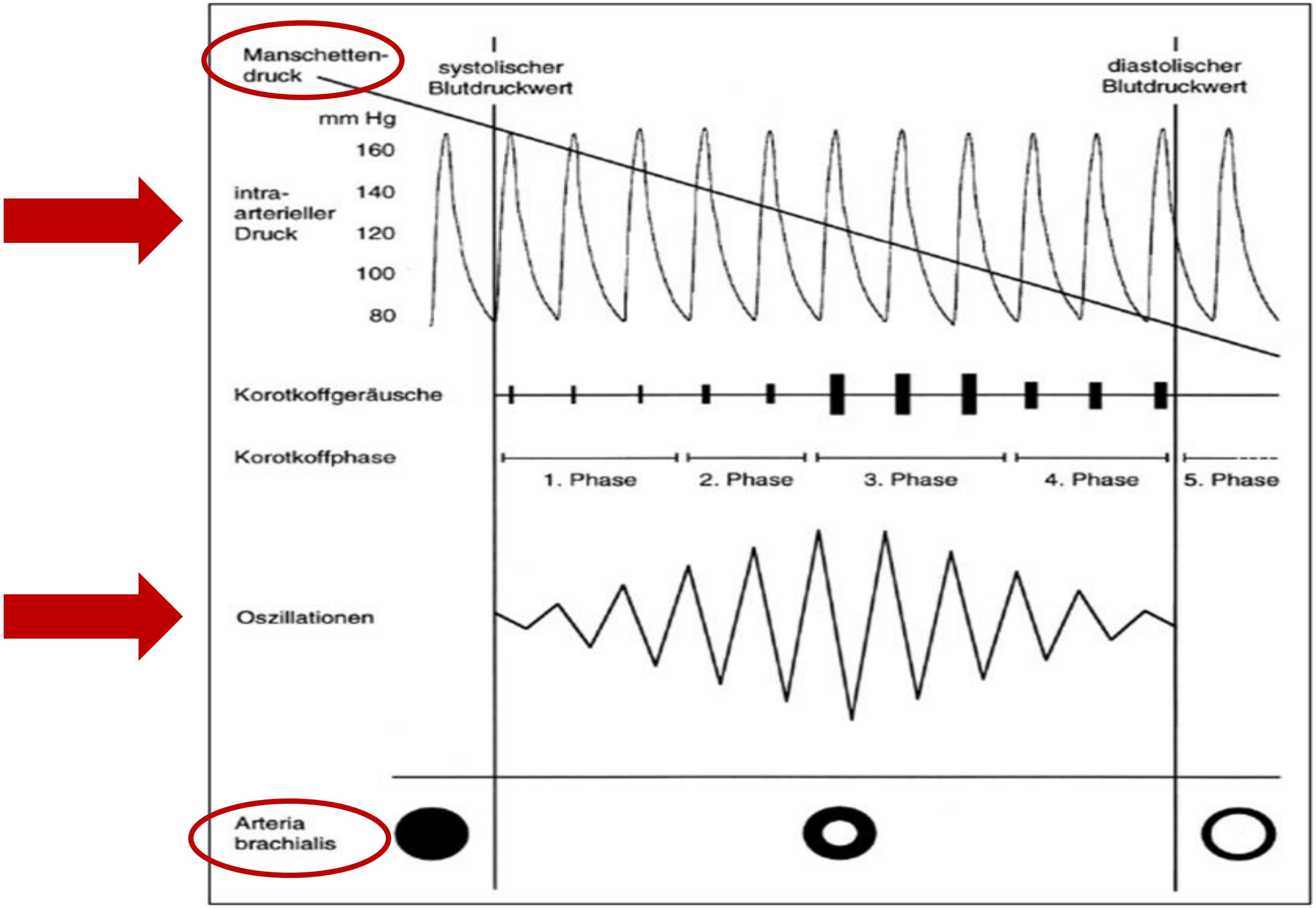

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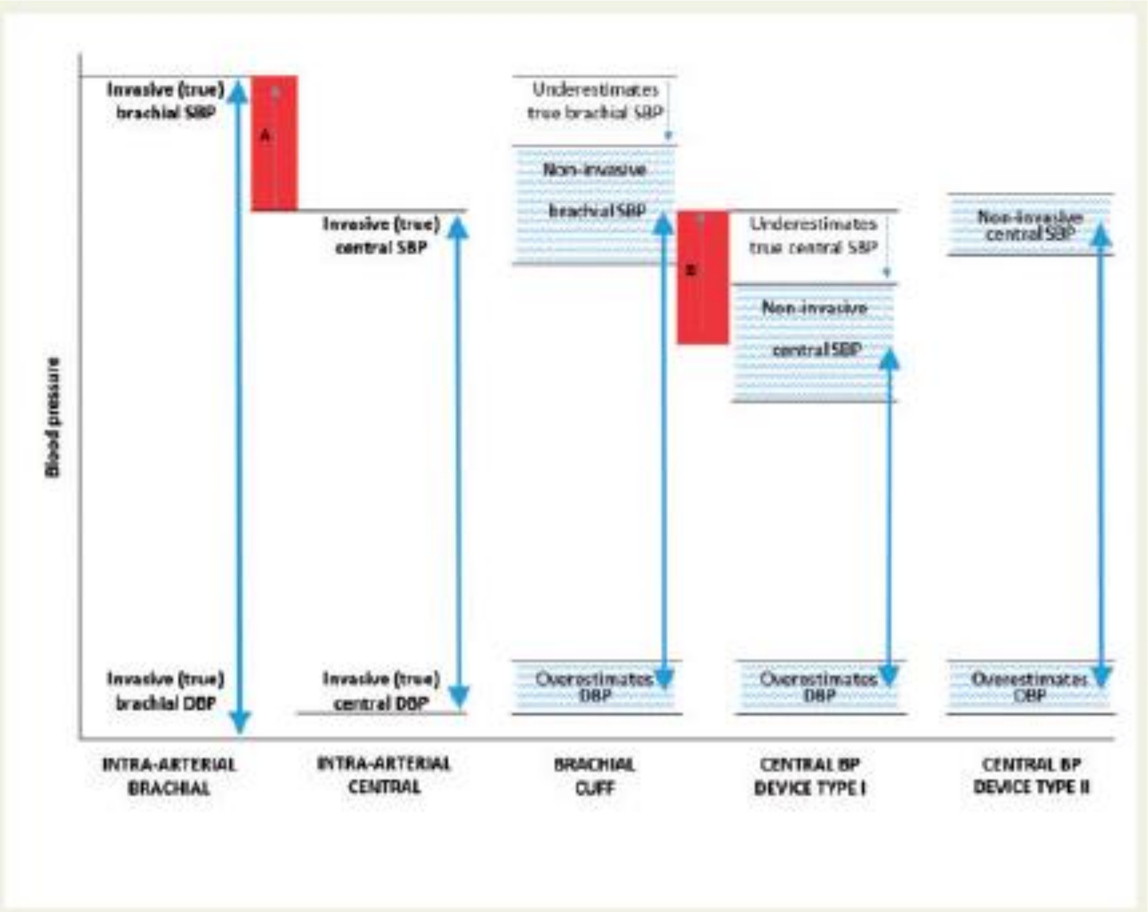
CONSEQUENCE (HEADACHE?)



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ACCURACY (MD OF +/- 5.0 MMHG)

Micromanometer-tipped catheters are the preferred instruments to use, but meticulously handled fluid-filled catheters may also be acceptable for accurately measuring intra-arterial BP.[61–63] For measure-

flushing protocol, sensor/s position on the catheter; how the manifold position was maintained at heart level (for fluid-filled devices where hydrostatic pressure may influence BP data); calibration/zeroing steps performed together with details of additional equipment used for this process where relevant (note: zero drift may still be a cause of imprecision when using micromanometer-tipped catheters);

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10 cm ~ 7-8 mmHg

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VARIABILITY (SD OF 8 MMHG)

Sample characteristics. A sample size of at least n = 85 adults is proposed based on brachial BP validation protocols and the requirement to detect a mean difference of 5 mmHg [standard deviation (SD) of the difference 8 mmHg] with an estimated power of >99% (two-sided alpha of 5%), as currently proposed by the AAMI standard. Nevertheless, invasive BP measures during clinical procedures face additional constraints that can increase BP variability, such as selective patient characteristics and limited time for repeat measurements. Thus, a definitive sample size based on robust statistical methods is still needed. If devices are to be used in paediatric age groups, then

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SD 7-15 mmHg in literature

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POWER BY SAMPLE

Difference	Sensitivity	Specificity	Standard Dev.	Sample size
5 mmHg	95%	95%	8	85
5 mmHg	95%	95%	9	105
5 mmHg	95%	95%	10	130
5 mmHg	95%	95%	11	155
5 mmHg	95%	95%	12	185

$$n = \frac{2 \times (z_{1-\alpha/2} + z_{1-\beta})^2 \times \sigma^2}{\Delta^2}$$

N = 2 x (2 + 2)^2 x 8^2 / **5^2** = 32 x 64 / 25 = 82

N = 2 x (2 + 2)^2 x 8^2 / **3^2** = 32 x 64 / 9 = 228

INTERVENTION

during device operation.[69] Thus, the main objective for validation testing of ambulatory BP monitors is to determine device performance under conditions of a change in BP and heart rate from the stable resting state. To this end, a variety of standardized interventions causing a statistically significant ($P < 0.05$) hemodynamic change for BP and heart rate, may be acceptable, for example administering a standard dose of glyceryl trinitrate,[9] table tilting, isometric hand grip exercise, or supine cycling.[31] Once the hemodynamic change has been initiated, performance of the non-invasive BP test device can be tested against the intra-arterial standard, as described for the resting state. Description of the intervention procedure must be reported.

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Intervention allows to increase power for given patient numbers

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MEAN PRESSURE / CALIBRATION

ate non-invasive estimation of central SBP.[43] Several methods may be used to derive MAP, including by calculation from potentially inaccurate brachial cuff BP [e.g. DBP + 1/3 (or 40%) pulse pressure,[44] or from integration of the pressure waveforms calibrated to cuff BP], or estimation from the peak oscillometric signal,[45] but information regarding the accuracy of these approaches is limited. Central BP indi-

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No standard defined!

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CALIBRATION BY SAMPLE

	Male (N=2276)		Female (N=5133)	
	Median	2.5 - 97.5 P	Median	2.5 - 97.5 P
Age (years)	54	24 - 83	54	20 - 81
HR (1/min)	76	54 - 104	76	58 - 103
bSBP (mmHg)	**131**	107 - 168	**124**	100 - 165
DBP (mmHg)	84	63 - 109	77	58 - 102
aSBP1 (mmHg)	**121**	98 - 153	**115**	92 - 153
MBP (osc, mmHg)	106	85 - 133	99	79 - 129
aSBP2 (osc, mmHg)	**133**	109 - 173	**125**	101 - 167
MBP (33%, mmHg)	100	80 - 126	93	74 - 121
aSBP3 (33%, mmHg)	**120**	98 - 152	**112**	90 - 147
MBP (40%, mmHg)	103	82 - 129	96	77 - 125
aSBP4 (40%, mmHg)	**127**	104 - 163	**119**	96 - 157

Baseline data (General population/pharmacies – cross sectional).

DETERMINANTS OF DIFFERENCES

	Coefficient	Std. Error	rpartial	P
aSBP1 - aSBP2				
Constant	-36,0170			
Sex	5,7493	0,9101	0,07323	<0,0001
Heartrate (HR)	0,4435	0,01997	0,2499	<0,0001
Sex*HR	-0,05635	0,01168	-0,05597	<0,0001
aSBP1 - aSBP4				
Constant	-33,7451			
Sex	5,6108	0,8147	0,07980	<0,0001
Heartrate (HR)	0,3679	0,01788	0,2326	<0,0001
Sex*HR	-0,04908	0,01046	-0,05447	<0,0001
aSBP1 - aSBP3				
Constant	-31,8869			
Sex	5,8954	0,7542	0,09048	<0,0001
Heartrate (HR)	0,2885	0,01655	0.1986	<0,0001
Sex*HR	-0.04908	0,009682	-0.05484	<0,0001

Determinants of differences between aSBP1 and aSBP2, aSBP4, aSBP3 with different MAP methods/form factors.

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Determinants of differences between aSBP1 and aSBP2, aSBP4, aSBP3 with different MAP methods/form factors.

MY CONCLUSIONS

- Invasive reference: TOP
- Use solid state catheters
- Plan interventions to increase power
- Standard for mean pressure needed

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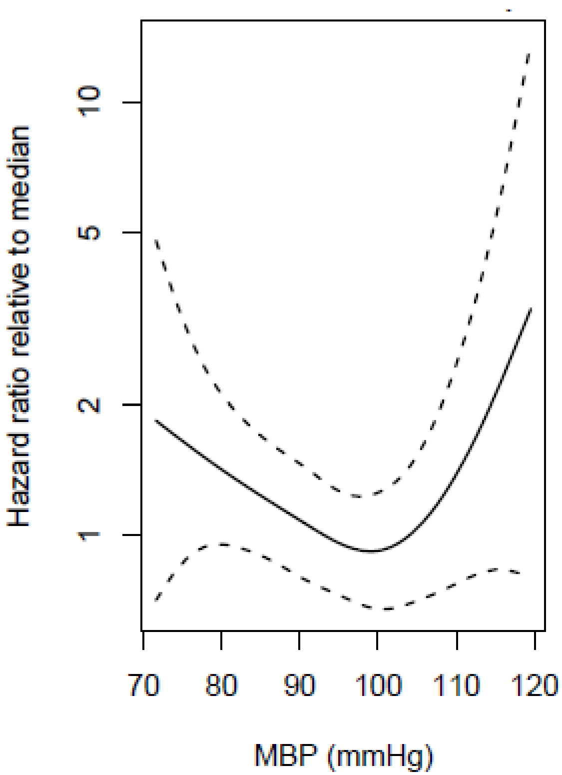
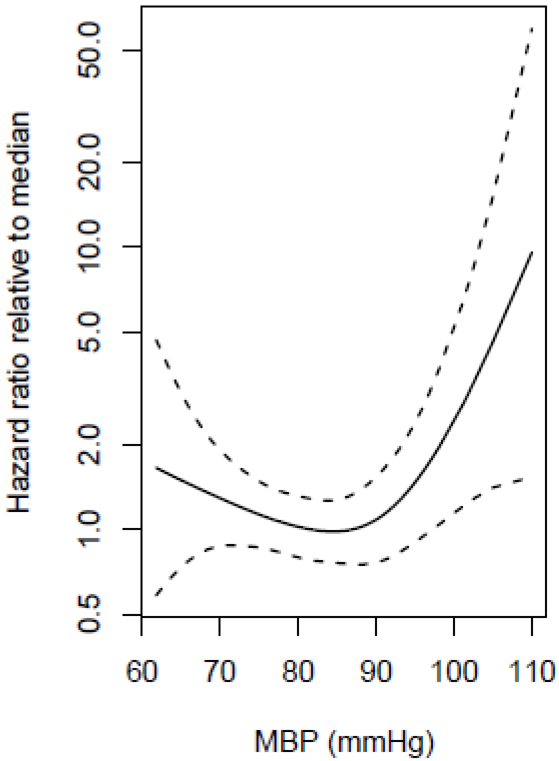
TOMORROW TODAY

THANK YOU!

OUTCOME – ALL CAUSE MORTALITY (ESRD)



33% rule



40 % rule

183 pts,3.5 years fu, 54 events