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ClearSight for postoperative arterial blood pressure monitoring after carotid endarterectomy: a validation study

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Disclosure

I have the following potential conflicts of interest to report:

☑ I do not have any potential conflict of interest

Introduction

- Carotid endarterectomy (CEA) → stroke risk due to intervention itself
- Half of all events are of hemodynamic origin
- To reduce this risk → strict BP control is required
- ESVS guidelines recommend to invasively measure BP 3-6h postoperatively

Introduction

- Radial artery cannula
  - Invasive beat-to-beat BP device
  - Complication risk
    - failure of cannulation
    - bleeding
    - pseudo-aneurysms
    - thrombotic embolization or occlusion
  - Expensive → admission recovery or medium care unit

- ClearSight system
  - Non-invasive beat-to-beat BP-device on finger
  - Easy-in-use + possible on ward
  - Intraoperative clearsight = radial arterial BP
  - **Alternative?**

Aim of study

The primary aim of this study was to determine the **accuracy** and **precision** of BP monitored by **ClearSight system (BP_{CS})** compared to **radial artery BP (BP_{RAD})** for postoperative blood pressure monitoring following CEA.

Secondary, we quantified the frequency of potential over- and undertreatment when invasive BP monitoring would be replaced by non-invasive ClearSight BP system.

Methods

Single-centre, prospective validation study

- 52 CEA patients
- July 2017 – June 2018 UMC Utrecht

Study design

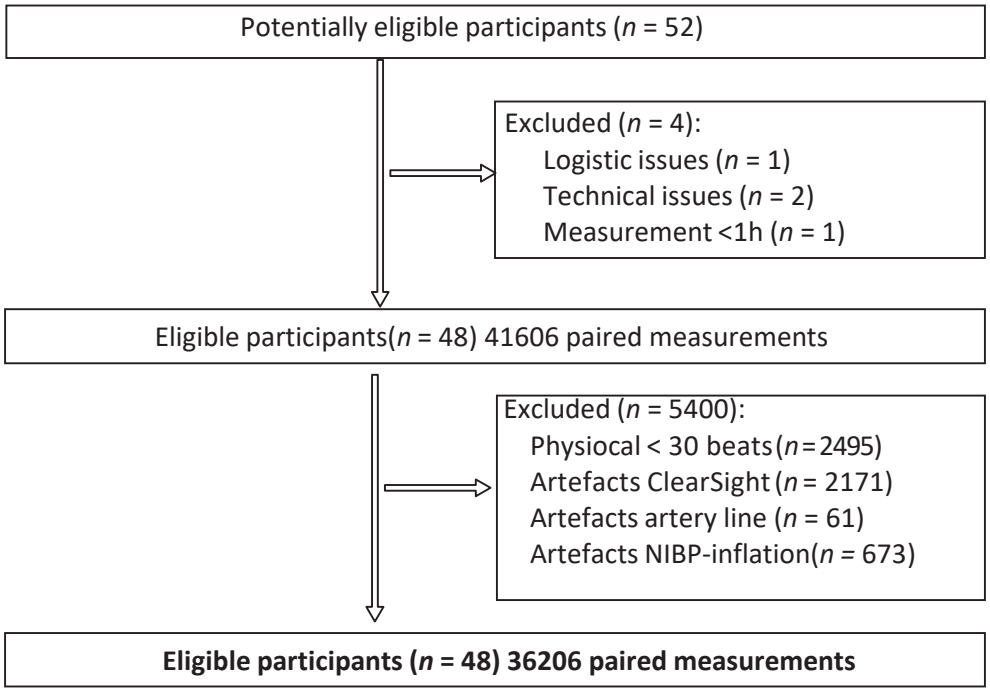
- BP_{CS} and BP_{rad} simultaneously ipsilateral
- 6 hours on recovery
- Individual systolic BP-restriction based on TCD increase (intra and 2h postoperative)

Methods

Data analyses

- BP_{cs} and BP_{rad} alignment in time
- excluded: artefacts due to flushing/NIBP/low physiocal
- 20 seconds slots

Results


Potentially eligible participants (n = 52)
Excluded (n = 4):
Logistic issues (n = 1)
Technical issues (n = 2)
Measurement <1h (n = 1)
Eligible participants(n = 48) 41606 paired measurements
Excluded (n = 5400):
Physiocal < 30 beats (n = 2495)
Artefacts ClearSight (n = 2171)
Artefacts artery line (n = 61)
Artefacts NIBP-inflation(n = 673)
Eligible participants (n = 48) 36206 paired measurements

	All patients (n=48)
Age	71.5 [50-93]
Sex, male	36 (75%)
Risk factors	
Hypertension	34 (71%)
Hyperlipidaemia	35 (73%)
Diabetes mellitus	13 (27%)
Coronary artery disease	20 (42%)
Peripheral arterial disease	11 (23%)
Smoker (current/ex)	36 (76%)
Symptomatic	48 (100%)
Ipsilateral stenosis	
50-70%	5 (10%)
>70%	42 (87%)
Contralateral stenosis	
Occlusion	10 (21%)
>70%	5 (10%)
50-70%	5 (10%)
<50%	28 (58%)
Shunt-use	5 (10%)
Medication	
Statins	39 (81%)
Antiplatelets	41 (85%)
Anti-coagulants	5 (10%)
Diuretics	12 (25%)
BP-lowering drugs	32 (67%)
Preoperative systolic BP, mmHg (SD)	147 (17)
Preoperative diastolic BP, mmHg (SD)	77 (12)
Preoperative MAP, mmHg (SD)	101 (11)

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Preoperative MAP, mmHg (SD)	101 (11)

Validation

Standard of AAMI:

Bias(precision) is <5(8)mmHg compared to reference → **clinically acceptable**

	Bias	Precision
Systolic BP (mmHg)	-9.58	13.64
Diastolic BP (mmHg)	7.92	7.19
MAP (mmHg)	4.00	7.78
Systolic BP (mmHg) (adjusted - baseline)	-9.58	14.05
Diastolic BP (mmHg) (adjusted - baseline)	7.92	6.47
MAP (mmHg) (adjusted - baseline)	4.00	7.74
Systolic BP (mmHg) (adjusted - baseline + pulse pressure)	-9.58	8.35
Diastolic BP (mmHg) (adjusted – baseline + pulse pressure)	7.92	6.53
MAP (mmHg) (adjusted - baseline pulse pressure)	4.00	7.52

Clinical decision making

Potential overtreatment: BP_{CS} **exceeds** systolic BP-restriction while Bp_{rad} ↓

Potential undertreatment: BP_{CS} **below** systolic BP-restriction while Bp_{rad} ↑

20s samples	**All**	**180 mmHg**	**160 mmHg**	**140 mmHg**	**120 mmHg**
Overtreatment, n (%)	860 (2.38%)	197 (0.72%)	114 (9.30%)	83 (2.07%)	466 (15.24%)
Undertreatment, n (%)	2103(5.81%)	447 (1.63%)	15 (1.22%)	816 (20.33%)	640 (20.93%)

Clinical decision making

Potential overtreatment: BP_{CS} **exceeds** systolic BP-restriction while BP_{rad} ↓

Potential undertreatment: BP_{CS} **below** systolic BP-restriction while BP_{rad} ↑

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5 min samples	**All**	**180 mmHg**	**160 mmHg**	**140 mmHg**	**120 mmHg**
Overtreatment, n (%)	69 (2.38%)	10 (0.46%)	6 (7.41%)	6 (1.91%)	45 (17.79%)
Undertreatment, n (%)	161 (5.55%)	31 (1.42%)	2 (1.85%)	61 (19.43%)	53 (20.95%)

Conclusion

Validity

- Non-invasive **MAP was similar** to invasive BP_{RAD} during postoperative observation following CEA, based on AAMI criteria.
- Systolic BP and diastolic BP **did not**

Clinical implication

- BP_{CS} → high percentages of undertreatment

Since systolic BP is leading in postoperative monitoring to adjust BP-therapy on, **BP_{cs} is not a reliable alternative** for BP_{RAD} in this clinical setting.

Thank you

Any questions?

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Discussion

- Limitations
  - Technical issues
  - Ipsilateral measurement → possible decreased blood flow finger
  - 5 of 49 uncomfortable tingling sensation

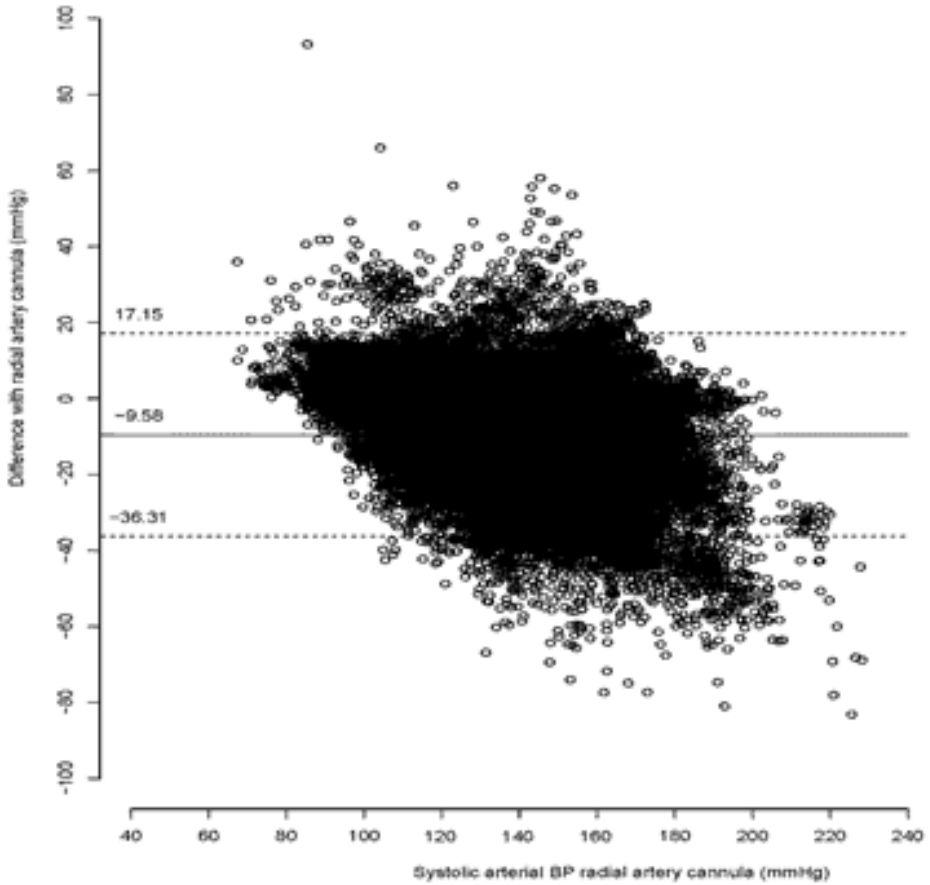
- ClearSight: non-invasive, easy-in-use, cheaper

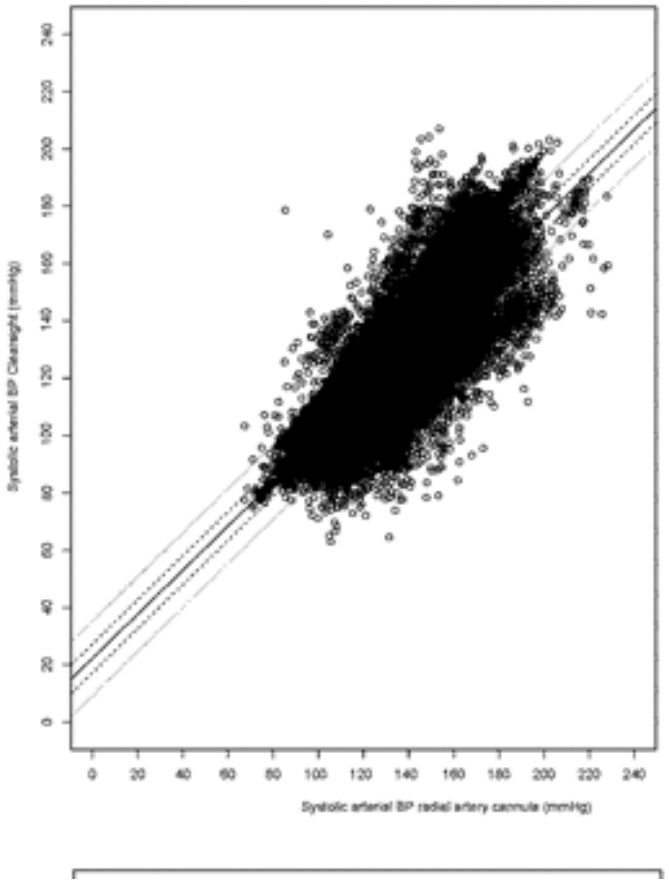
- Specific recommendations for postoperative BP thresholds are lacking
  - *MAP monitoring in future?*

Results

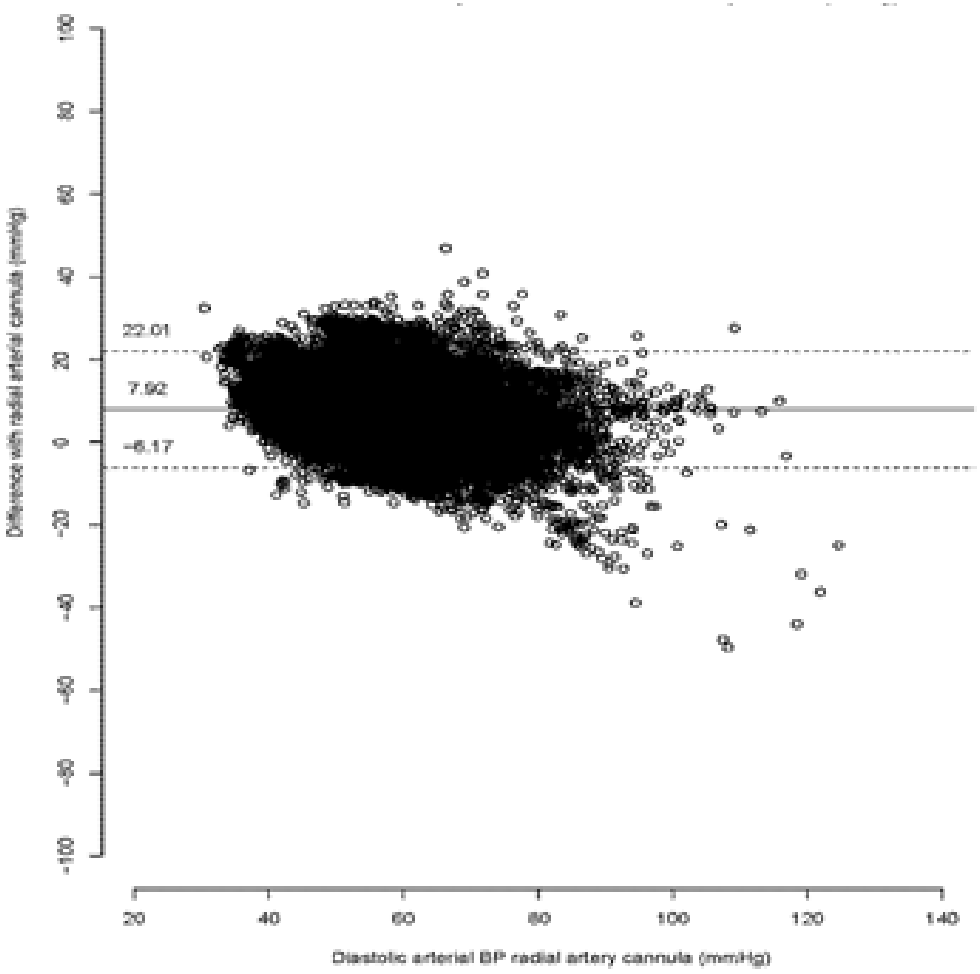
	All patients (n=48)
Total events	7 (15%)
- Cerebral hyperperfusion	3 (6%)
- Bleeding requiring surgery	1 (2%)
- Stroke	1 (2%)
- TIA	2 (4%)
Medium care admission	8 (17%)
Extended recovery admission	11 (23%)
Labetalol-use	11 (23%)
Norephedrine-use	4 (8%)
Clonidine use	6 (13%)

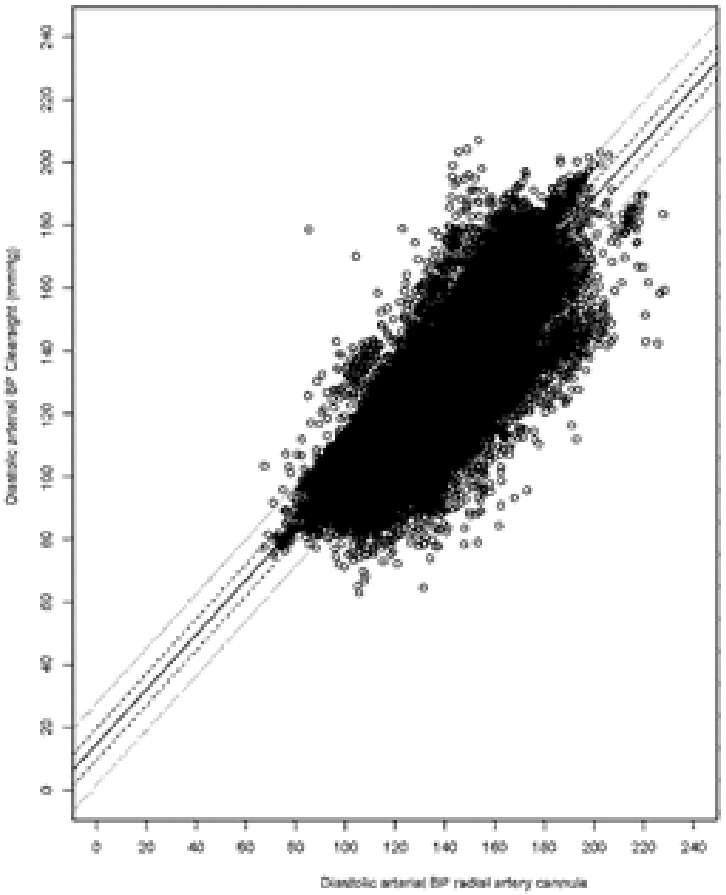
A


Difference with radial artery cannula (mmHg)
100
80
60
40
20
0
-20
-40
-60
-80
-100
17.15
-9.58
-36.31
40
60
80
100
120
140
160
180
200
220
240
Systolic arterial BP radial artery cannula (mmHg)

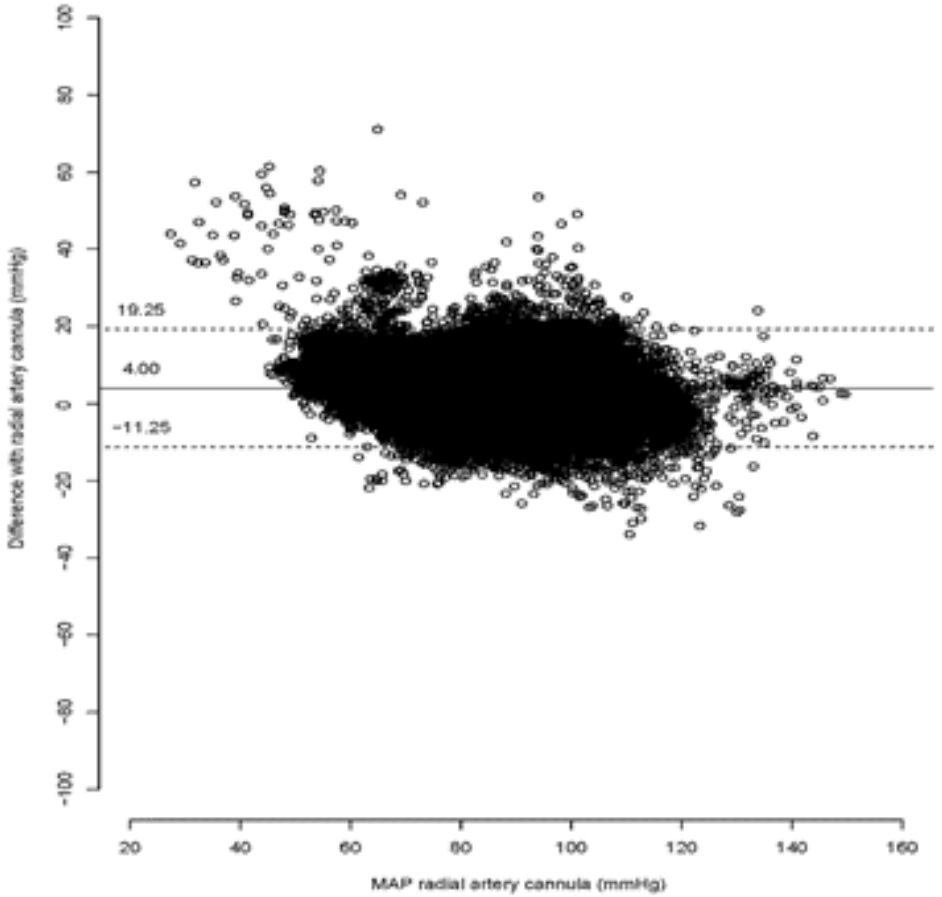

Systolic arterial BP Cleanright (mmHg)
0
20
40
60
80
100
120
140
160
180
200
220
240
Systolic arterial BP radial artery cannula (mmHg)

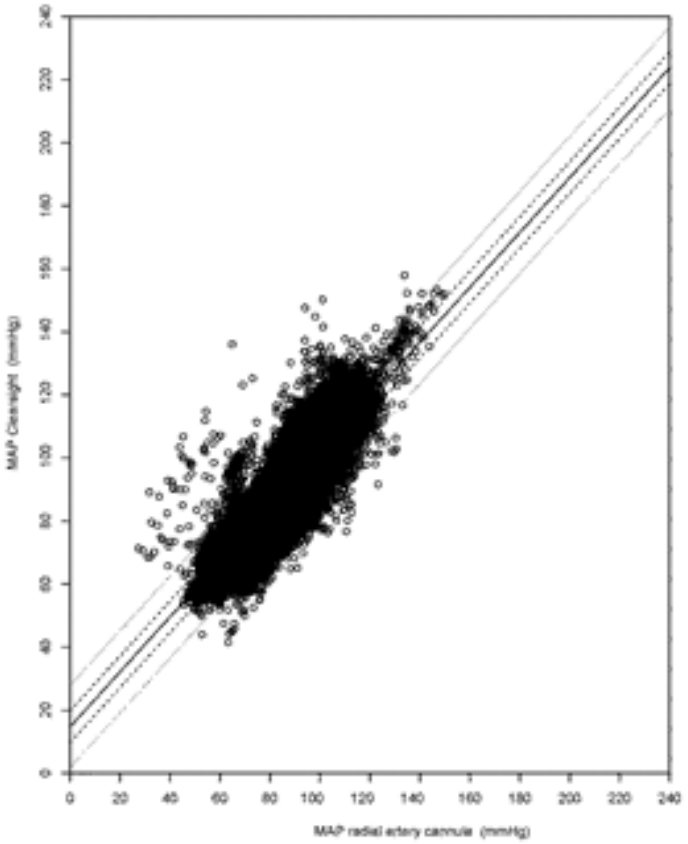
B

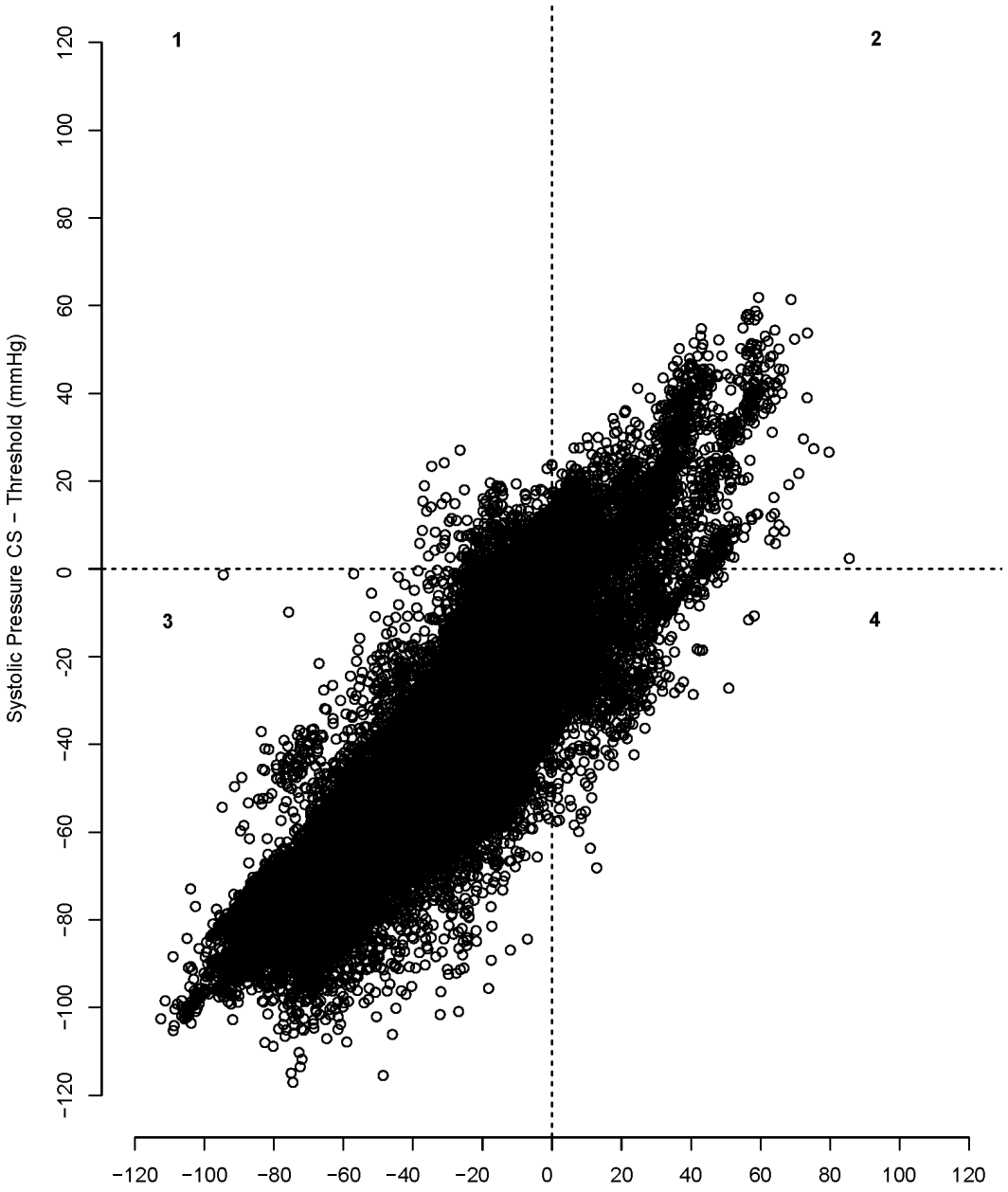

22.01
7.92
−6.17
Difference with radial arterial cannula (mmHg)
Diastolic arterial BP radial artery cannula (mmHg)


Diastolic arterial BP Clearsight (mmHg)
Diastolic arterial BP radial artery cannula

C


19.25
4.00
−11.25
Difference with radial artery cannula (mmHg)
MAP radial artery cannula (mmHg)


MAP Clearsight (mmHg)
MAP radial artery cannula (mmHg)


1
2
3
4
Systolic Pressure CS − Threshold (mmHg)
120
100
80
60
40
20
0
−20
−40
−60
−80
−100
−120
−120 −100 −80 −60 −40 −20 0 20 40 60 80 100 120
Systolic arterial pressure − threshold (mmHg)