

UiT

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Traumeforskning i Norden de siste 20 år

En systematisk litteraturgjennomgang

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Forord

Med prosjektet "Traumeforskning i Norden" har vi gjort en systematisk gjennomgang av forskning på traumebehandling utført i Norden de siste 20 år. Prosjektet spinner ut fra et observert behov fra fagfolk og forskere som jobber med traumatologi, der man har identifisert mangel på en oversikt over forskningen som er utført. Det er stilt spørsmål ved hvilke deler av behandlingskjeden som har blitt viet mest forskningsfokus, og således har det vært uklart hvilke områder som bør gjøres til gjenstand for mer forskning.

Fagområdet traumatologi griper inn i alle deler av pasientbehandlingen, og representerer således utfordringer hva angår å optimalisere pasientforløpene og ivareta pasientsikkerheten.

Prosjektet Traumeforskning i Norden ble opprinnelig innledet i 2015 av lege Ingrid Schrøder Hansen og professor Torben Wisborg. Undertegnede fikk i 2017 mulighet til å ta del i, og sluttføre, prosjektet som en del av medisinstudiets emne "MED-3950 Masteroppgave" ved Universitetet i Tromsø – Norges arktiske universitet. Nasjonal kompetansetjeneste for traumatologi (NKT-T) har bidratt med reiseutgifter i forbindelse med møter i arbeidsgruppen. Universitetet i Tromsø – Norges arktiske universitet (UiT) har dekket utgifter for bruk av det nettbaserte screeningsverktøyet Covidence (1).

Det rettes en stor takk til veilederne og førstebibliotekar Eirik Reierth ved UiT, samt førsteamanuensis Trond Iversen ved ISM UiT. Uten deres kyndige veiledning og hjelp hadde ikke dette prosjektet kunne vært gjennomført.

Tromsø, 4. Juni 2018



Valdemar Vea Iversen

1 Sammendrag

Bakgrunn og formål Alvorlige hendelser er over hele verden en viktig årsak til død hos personer under 45 år. Mortalitet etter alvorlige traumer er høy. De nordiske landene skiller seg fra resten av verden med sitt kalde klima og store avstand. I tillegg er tettheten av store sykehus lav. Det har vært poengtert fra forskere og fagmiljø at behovet for forskning innenfor fagområdet traumatologi er mangelfull, og at mer forskning kreves. Vi ønsket å undersøke og beskrive forskningen som er utført i traumatologisk sammenheng i de nordiske land fra 1995 og fram til i dag.

Materiale og metode I samarbeid med erfaren bibliotekar utførte vi et systematisk søk i alle relevante databaser for traumeforskning i Norden i perioden 1995 og til dagens dato. Etter fjerning av duplikater ble 5117 artikler screenet på tittel og abstrakt i forhold til definerte inklusjons- og eksklusjonskriterier. Etter fulltekstvurdering ble 844 artikler inkludert, og variabler registrert. Det ble registrert variabler for årstall, land, behandlingskjede, skadetype og forskningsdesign.

Resultater I observasjonsperioden er det registrert en jevn økning i antall publikasjoner. Fordelingen av publikasjoner er relativt lik mellom Norge, Sverige og Danmark. Finland og i særdeleshet Island publiserer mindre. Man finner en overvekt av kohort-studier i materialet, mens det foreligger svært få randomiserte kontrollerte studier. Studier av de ulike behandlingsleddene domineres av epidemiologiske studier, mens andre ledd er mindre beskrevet. Av de andre leddene i behandlingskjeden er prehospital forskning utført omtrent tre ganger hyppigere enn forskning på andre ledd i kjeden.

Konklusjon Oppgaven har pekt ut områder innenfor traumatologien som er mangelfullt beskrevet. Dette dreier seg i hovedsak om forskning på isolerte alvorlige skader i traumesammenheng. Det er identifisert lite forskning på hva som skjer med traumepasienten ved overføring til ordinær sengepost i sykehuset. Det er av interesse å sammenholde funnene med internasjonal forskning, da man kan tenke seg at de identifiserte manglene dekkes opp av internasjonal forskning der overføringsverdien av funnene er stor.

2 Innledning

2.1 Bakgrunn for oppgaven

Allerede før oppstart på medisinstudiet fikk jeg en interesse for behandling og håndtering av tilskadekomne pasienter. Gjennom deltidjobb i ambulansetjenesten og etter hvert arbeid i sykehuset er interessen, og innsikten, i det sammensatte fagområdet ”traumatologi” styrket. Det var således naturlig å velge en oppgave innenfor akuttmedisin eller traumatologi når denne oppgaven skulle skrives.

Som medisinstudent kan man få inntrykk av at man gjennom utdanningsløpet gradvis lærer seg allerede innarbeidete og etablerte sannheter. Parallelt med prosesjon i studiet forstår man at alle fagområder er dynamiske, og således kan alle leger og annet helsepersonell være med å drive fram kvalitet i arbeidet man utfører. For fagområdet traumatologi har det i de senere år vært et stadig økende fokus på kvalitet i tjenesten, spesielt hva angår implementering av retningslinjer og standardisert håndtering av pasientene uavhengig av hvor man bor eller hvilket sykehus man tilhører (2).

Denne oppgaven er en del av forskningsprosjektet ”Trauma research in the Nordic countries”. Hovedhensikten med denne deloppgaven har vært å kartlegge den samlede nordiske traumeforskningslitteraturen publisert i perioden 1995-2018. Denne litteraturen forventer vi beskriver traumeforskningens bredde, og den antas også å utgjøre kunnskapsgrunnlaget for dagens traumebehandling og traumesystem i de nordiske landene.

Gjennom samtaler og innledende møter kom vi fram til at undertegnede kunne skrive denne oppgaven med Torben Wisborg som hovedveileder og Elisabeth Jeppesen som biveileder. Wisborg er professor ved IKM UiT og overlege i anestesiologi ved Finnmarkssykehuset. I tillegg er Wisborg leder for Nasjonal kompetansetjeneste for traumatologi. Jeppesen er utdannet sykepleier med mastergrad i folkehelsevitenskap fra UiT og doktorgrad fra UiO. Hun er leder for nasjonalt traumeregister.

2.2 Grunnleggende om traumatologi

Alvorlige hendelser er uforutsigbare og inntreffer gjerne på tider og steder der apparatet for å håndtere hendelsene ikke er optimale. Alvorlig skade er en vesentlig bidragsyter til for tidlig død og nedsatt funksjon for de som blir rammet. Til forskjell fra mange andre tilstander og sykdommer rammer ulykker mer vilkårlig, og det er ofte

unge mennesker involvert. For å redusere sykdomsbyrden etter en alvorlig ulykke er det essensielt med gode og forberedte behandlingssystemer (3).

Problemene omkring alvorlig skadde pasienter er ikke en ny problemstilling, da skader i alle tider må ha vært en vesentlig bidragsyter til for tidlig død og alvorlig funksjonsnedsettelse. Etter hvert som det moderne helsevesenet har utviklet seg har det kommet stadig nye metoder for å redusere sykdomsbyrden etter en alvorlig skade.

Håndteringen av skadde pasienter har et moment som ikke er like fremtredende i andre deler av medisinen, nemlig tidsaspektet. Ved alvorlig skade blir tidsfaktoren og tid til definitiv behandling svært viktig, dette utfordrer de tradisjonelle behandlingssystemene, der tid ofte kan betraktes som en del av diagnostikken. I traumesammenheng kreves oftere resolutt inngripen for å reversere patologiske prosesser i legemet som vil føre til død eller alvorlig funksjonstap hvis man ikke intervenerer (3).

Dette innebærer at alvorlig skadde pasienter må håndteres annerledes enn andre pasientgrupper. For å redusere mengden unngåelige dødsfall må systemene som skal håndtere pasientene være annerledes organisert enn det øvrige helsetilbudet, der man kan bestille time og vente på venterommet til legen er klar. Dette gir også behov for egen forskning på problemstillingene som er særegne for traumepasientene, men også de deler av helsetjenesten som må bruke sine vanlige rutiner på en annen måte hos en hardt skadd pasient enn hos andre pasienter. Traumeforskning er forskning som spesifikt retter seg mot håndtering og behandling av alvorlig skadde pasienter, der tid og riktig håndtering er essensielt for best mulig resultat (3). Som i alle fagområder av medisinen er forskning essensielt for å sikre kvaliteten i behandlingen man gir. Det er av vesentlig betydning å begrunne sine prosedyrer og rutiner i etablert forskning.

2.3 Traumatologi og traumebehandling på sykehus

Alvorlige traumer er over hele verden en viktig årsak til død hos personer under 45 år. På verdensbasis er mortalitet forbundet med alvorlige traumer angitt til å være 73/100.000 i 2012 (4). I de nordiske landene er den estimerte mortalitetsraten 23-29/100.000 i 2012 (4). De nordiske landene skiller seg fra resten av verden med sitt kalde klima og store avstander. Befolkningen bor spredt, og tettheten av store sykehus er lav (5). De nordiske landene er preget av god økonomi, og dermed et godt utbygd helsevesen. Antallet alvorlige traumer er generelt sett lite, og de enkelte sykehus har et

lite antall alvorlig skadde pasienter hvert år (5). Alvorlig skadde pasienter skal helst behandles på sykehus definert som traumesenter. I dette ligger en rekke kriterier som skal være oppfylt, herunder spesifikke krav til tilgang på relevante kirurgiske spesialiteter og alle nødvendige støttefunksjoner beskrevet i en såkalt traumeplan. I praksis vil dette tilsvare de største sykehusene. De nordiske landene har få sykehus som er definert som traumesenter (6).

På bakgrunn av dette kan man anta at forskning på håndtering av traumepasienter i Norden byr på andre utfordringer enn andre steder i verden, der hyppigheten av alvorlige traumer og tettheten av traumesenter er større. Tradisjonelt har man observert stor variasjon i håndtering av traumepasientene i de nordiske landene, uten at dette nødvendigvis har vært forankret i implementerte rutiner og prosedyrer (7). Det har vært en trend at mye av behandlingen har vært preget av tradisjon, og i mindre grad moderne, systematisk og evidensbasert medisin (7).

De siste årene har det imidlertid vært et økende fokus på god håndtering av traumepasienter og gode kvalitetssikrede systemer for mottak av alvorlig skadde pasienter(8). Det har i Norden vært gjort mange tiltak for å forsøke og kvalitetssikre traumebehandlingen, for eksempel ved bruk av videokommunikasjon mellom sykehus (9) innføring av traumesystemer (10) og systematisert teamtrening (11).

2.4 Akuttmedisin og traumesystemer

Et traumesystem defineres i helsevesenet som ”en organisering av alle ressurser i den kjeden som behandler den alvorlig skadde pasient, der sømløs overlapping og informasjonsflyt tilstrebtes i et system uten terskler eller flaskehals” (3) . Et traumesystem er ofte nedfelt i en traumeplan ved de enkelte sykehusene.

Den vanlige gangen i en akuttmedisinsk alvorlig hendelse er at dette varsles til et akuttmedisinsk nødnummer, i Norge til akuttmedisinsk kommunikasjonssentral (AMK). Telefonoperatørene forholder seg til fastsatte algoritmer nedfelt i den såkalte Norsk Index for akuttmedisin (12) for å kartlegge grad av alvorlighet og skadeomfang, slik at adekvat respons kan iverksettes.

Ved alvorlig skade vil dette medføre utalarmering av prehospitalie helsetjenestetilbydere som ambulansetjenester og/eller lokale legevakter. Etter at den akutte responsen er ivaretatt skal sykehussystemet være klart til å motta den skadde pasienten. Den

primære oppgave i sykehuset er å gjennomføre umiddelbare livreddende tiltak for å opprettholde vitale funksjoner, sikre korrekt diagnostikk, iverksette adekvat behandling og monitorere pasienten (3).

2.5 Rehabilitering etter traume

Rehabilitering etter traumer og skader har en helt sentral plass i moderne traumebehandling, og spesialiserte rehabiliteringsenheter skal så raskt som mulig gi adekvat opptrening for å bidra til gjenvinning av god funksjon. I Norden er mange spesialressurser samlet til sykehus med nasjonal funksjon. For eksempel er St. Olavs Hospital i Trøndelag nasjonalt senter for avansert bekkenkirurgi, mens Sunnaas sykehus i Oslo er nasjonalt senter for rehabilitering av blant annet denne pasientgruppen. Pasienttransport mellom de ulike sykehusene med slike spesialistfunksjoner vil derfor være en stor utfordring. Effektiv og faglig god transport mellom de ulike nivåene i behandlingskjeden blir derfor et kritisk problem for god oppfølging av traumepasienter. Av samme årsak er "transportmedisin" etter hvert blitt et eget begrep, der spesialpersonell har kompetanse og utstyr for transport av kritisk syke pasienter langs vei eller i luften (13).

2.6 Traumemottak

Ett traumemottak er en forberedt og på forhånd definert måte å ta imot en mistenkt eller bekreftet alvorlig skadd pasient på. I Norge er det mange sykehus som mottar alvorlig skadde pasienter. Mellom sykehusene kan det være noe forskjell på organisering og tilgjengelig personell ved mottak av en alvorlig skadd pasient, men de overordnede prinsippene skal være de samme (3). Ved en alvorlig hendelse med mistenkt alvorlig personskade er det utarbeidet ett sett kriterier (3) som gir indikasjon for utalarmering av traumeteam i sykehuset. Disse kriteriene er kjent for personell som arbeider i ambulansetjenesten prehospitalt, og brukes aktivt for å vurdere om vitale parameter eller skademekanisme tilsier at det kan foreligge en alvorlig tilstand. Hvis man finner indikasjon for dette varsles AMK fra skadestedet og AMK og/eller akuttmottakene kan deretter utløse en såkalt traumealarm i de respektive sykehusene. Dette fører til at en på forhånd definert gruppe av personell møter opp i akuttmottakets skadestue før pasienten ankommer. Med noen variasjoner innebærer dette teamleder, undersøkende kirurg, anestesilege, ortoped, radiolog, bioingeniør, anestesisykepleier og operasjonssykepleier (14). Personellet skal være samkjørt og trent i utførelsen av den

innledende undersøkelsen og behandlingen av den alvorlig skadde pasienten. Det skal være kjent for deltakerne i traumeteamet hvilke oppgaver som påligger det enkelte personell, og personellet skal være kjent for hverandre. Mottaket av pasienten følger definerte behandlingsalgoritmer, kjent som Advanced Trauma Life Support, ATLS (15). Dette er et etter hvert utbredt konsept for å systematisk tilnærme seg den skadde pasienten. Undersøkelsen baserer seg på en systematikk som kan anvendes på alle pasienter. Ved å undersøke etter de såkalte ABCDE-prinsippene sikrer man at de mest livsnødvendige funksjonene som åndedrett og sirkulasjon undersøkes først (16). Det er en krevende øvelse å gjennomføre et godt traumemottak, spesielt hvis hyppigheten av traumer i de enkelte sykehus er lav. Det er en utbredt oppfatning i fagmiljøet om at trening og simuleringstrening er viktig for å være forberedt når alarmen går (17). I Norge har stiftelsen BEST: Bedre og systematisk traumebehandling (Nå: BEST: Bedre & Systematisk Teamtrening) gjennom mange år gjort et iherdig arbeid for implementering av god etterlevelse av retningslinjer og rutiner i traumemottak (18).

2.7 Traumeforskning

I 2005 ble behovet for traumeforskning tatt opp av Roberts et al (19). Han hevder at traumebehandling er en sammensatt medisinsk intervasjon med mange aktører fra ulike helseprofesjoner. Mange ulike profesjoner har derfor forskningsinteresser innenfor fagområdet traumatologi. Problemstillingene i traumeforskingen blir derfor sammensatt ut fra hvilket behandlingsperspektiv som legges til grunn.

Det foregår en stadig økning av akademisk kompetanse i hele behandlingskjeden, også for fagutøvere som ikke er leger. Dette gjør at stadig flere utfører forskning, og har akademisk interesse innenfor fagområdet traumatologi. Dette kan gi opphav til forskyvning av fokus, samt variasjon i kvalitet i det forskningsarbeidet som utføres. Som allerede nevnt er det mange sykehus som hver for seg håndterer et lite antall alvorlig skadde hvert år. Dette kan gjøre at gjennomføring av forskningsprosjekter på de enkelte sykehus blir vanskelig på grunn av lavt antall traumepasienter. Alvorlig skadde pasienter er heller ikke i posisjon til å samtykke til datainnsamling i den akutte fasen av sitt forløp. I mange tilfeller vil det være etisk betenklig å gjøre kliniske studier på alvorlige skadde pasienter, da volumet er lite og forskjellene i forløpene representerer stor variasjon (20). Det er også metodiske utfordringer med å sette opp gode forskningshypoteser. Store forskningsprosjekter er tidkrevende og ressurskrevende.

Når man planlegger et forskningsprosjekt i klinikken er dette ofte på bakgrunn av et observert behov for mer kunnskap på et felt. I tillegg er det ofte interessant å demonstrere forskjell på to ulike behandlinger, der man kan vise at den ene er bedre enn den andre. Denne typen forskning er essensiell for å utvikle det medisinske faget som helhet. I traumesammenheng kan det være vanskelig å sette ulike behandlinger opp mot hverandre, da tiden ofte er knapp, og man alltid søker å gi den beste behandling. Ut fra dette følger det at forskningen kan bli sett på som mindre "attraktiv", noe som kan vanskeliggjøre finansieringen og således gjennomføringen av traumeforskning.

Et av tiltakene som er gjort i Norge for å forbedre forskningsinnsatsen er innføringen av det såkalte "traumeregisteret" (21). Registeret er etter mange års arbeid implementert i sykehusene, og skal således kunne tilby mer data for bruk i forskning. Gjennom systematisk registrering og bruk av den såkalte Injury Severity Score (ISS) åpnes det muligheter for å følge opp effekt og konsekvens av behandling av de ulike tilstandene som forekommer hyppigst ved alvorlig skade (22).

2.8 Kvalitet i traumeforskning

En vanlig måte å rangere kvaliteten i forskning på er ved hjelp av den såkalte "6S-pyramiden" utarbeidet av DeCenso og medarbeidere (23). Modellen er utarbeidet som en veileding for å gjennomføre vitenskapelige søk for å finne svar på kliniske problemstillinger. I toppnivået ligger "systems", deretter i nedadgående rangering "summaries", "synopses of syntheses", "syntheses", "synopses of studies" og til slutt "studies". Når man gjennomfører søk er det anbefalt å begynne på det høyeste nivået som representerer "systems". Dette er integrerte databaserte systemer som linker sammen all tilgjengelig informasjon der man kan legge inn spesifikke pasientdata, og således få svar på problemstillingen man står ovenfor i den kliniske hverdagen. Dette er enda lite utbredt, slik at man må bevege seg over til "summaries". Dette kan for eksempel være oppdaterte lærebøker som omtaler spesifikke problemstillinger, eller nettbaserte løsninger som kontinuerlig oppdateres med evidensbasert kunnskap. Dette vil også omfatte det vi kjenner som nasjonale retningslinjer for bruk i klinisk praksis. Der dette ikke foreligger benyttes oppsummeringer av systematiske reviews, kjent som metaanalyser. Metaanalyser summerer opp all tilgjengelig forskning på en spesifikk klinisk problemstilling. Metaanalyser baserer seg i det vesentlige på såkalte systematiske reviews. Systematiske reviews er i seg selv gode kilder til kunnskap hvis

ikke metaanalyser er tilgjengelig. Dette er oppsummert forskning som baserer seg på enkeltstudier eller synteser av enkeltstudier, såkalte litteraturstudier. Enkeltstudier, for eksempel kohortstudier eller randomiserte kontrollerte studier, er den primære kilden til kunnskap. Enkeltartikler kan imidlertid være vanskelig å vurdere da de ikke nødvendigvis sammenholdes systematisk med all annen tilgjengelig forskning på området.

Randomiserte kontrollerte studier (RCT) er gullstandarden for forskningsprosjekter fordi randomisering fører til at det ikke er systematiske forskjeller mellom gruppene man tester. Dette er viktig for å skape såkalte like grupper, der utfallet ikke er en konsekvens av systematisk skjevhets i utvalget. I kohort-studier er studiepopulasjonene basert på bakgrunn av eksposisjonen, deretter følger man disse pasientene og ser hvordan det går. Kasus-kontroll studier definerer studiepopulasjonene på bakgrunn av utfallet. Kasusserier eller pasientserier følger en gruppe pasienter uten noen kontrollgruppe for å evaluere hvordan det går med disse pasientene. Kasusrapporter er enkeltrapper som beskriver en konkret behandling, kasus eller hendelse forfatterne har et ønske om å formidle. Dette kan typisk være et behandlingsforløp der man har detektert en uvanlig tilstand, eller gjennomført en spesiell behandling. Grunnet traumatologiens sammensatte natur som diskutert tidligere, er det for dette fagområdet nærliggende å tenke at det kan være utfordrende med tradisjonelle kliniske studier. Hvis primærstudier i traumeforskning er av lav evidensgrad vil det implisitt følge at tilgangen på sekundærlitteratur nødvendigvis er begrenset.

2.9 Forskingsspørsmål i prosjektet "Trauma Research in the Nordic Countries".

Formålet med denne studien er å identifisere hvilken forskning som er gjort på området traumatologi i de nordiske landene de siste 20 år. Vi ønsker å undersøke og beskrive hvilken forskning som er utført i de nordiske land. Internasjonal forskning på de konkrete behandlingstiltak for ulike skader er nok overførbart til nordiske forhold, men det er mindre sannsynlig at forskning på logistikk og traumesystemer kan overføres direkte.

Vi ønsker å belyse de fem følgende forhold i denne oppgaven:

Har det vært en økning i traumeforskning i de nordiske landene de siste 20 årene?

I hvilke nordiske land er traumeforskningen størst?

Hvilken del av behandlingskjeden er det forsket mest på?

Hvilke skadetyper er beskrevet i traumeforskningen?

Hvilke forskningsdesign er mest brukt i traumeforskningen ?

Ved å besvare disse spørsmålene vil man kunne avklare hvilke områder som er tilgodesett med lite eller mangelfull forskning. Det er også av vesentlig betydning å beskrive forskningsdesignene i de studiene som er utført. På grunn av lav insidens av traumer på de enkelte sykehus i Norden er det sannsynlig at mye av forskningen som utføres er kasuistikkbasert og av retrospektiv type. Vår hypotese er at dette har medført en systematisk skjevhetsgrad i traumeforskningen. Hensikten med denne studien er å avdekke hvilke områder i traumebehandlingen som det er forsket lite på, og som bør gjøres til gjenstand for ytterligere forskning de kommende år. Det vil ikke være hensiktsmessig å vurdere kvaliteten i de enkelte studiene, siden antall studier er høyt, og dette ikke vil tilføre vesentlig informasjon om de store linjene i forskningen.

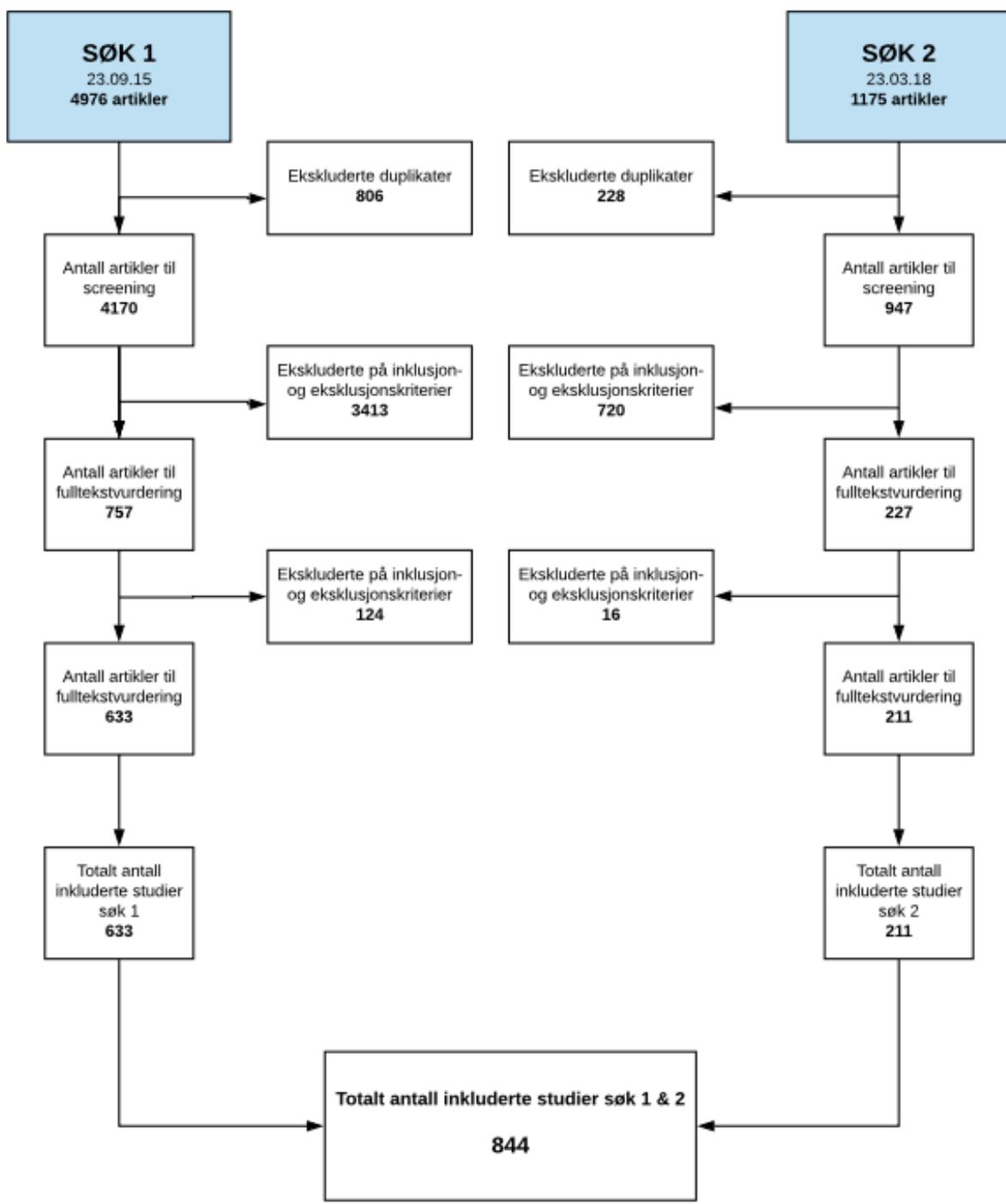
Oppgaven er således ikke ment for å problematisere den allerede utførte forskningen, men kan fungere veiledende for hvilken forskning som bør utføres i fremtiden, samt hvilke områder i behandlingskjeden som bør vies mer fokus i den videre traumeforskningen.

3 Materiale og metode

Prosjektet ble innledd med et omfattende databasesøk i samarbeid med erfaren bibliotekar ved Universitetsbiblioteket, UiT. Det første søket ble gjennomført i 2015 og data ble senere oppdatert med et nytt søk i de samme databasene i april 2018. I samarbeid med bibliotekar ble det utferdiget et systematisk søk i følgende databaser: Medline, Embase Cochrane Library, ISI web of science og Scopus. Vi benyttet Medline for å fastsette MeSH-termer, inkludert undertitler og publikasjonstyper i kombinasjon med Emtree index fra Embase. MeSH/Emtree- termer ble brukt i databaser uten kontrollerte indeks av søketermer, som ISI Web of Science og Scopus (Vedlegg 1). I tillegg er det gjennomført et åpent, trunkert, søker i alle databaser i søkefeltene "abstrakt", "tittel" og "nøkkelord".

Det første søket returnerte 4170 referanser som ble screenet av to medarbeidere, Jeppesen og Hansen, uavhengig av hverandre. Det oppdaterte søket returnerte 947 referanser, og ble screenet av Iversen og Jeppesen uavhengig av hverandre. Søket returnerte således totalt 5117 referanser som gikk til screening på tittel og abstrakt. Hver medarbeider tok stilling til om referansen var relevant i henhold til inklusjons- og eksklusjonskriteriene predefinert i forskningsprotokollen. Det var ingen uenigheter mellom medarbeiderne i inklusjonen av artiklene (Figur 1)

Fulltekstartikler i det første søket ble i hovedsak gjennomgått av Hansen, og dels Iversen. Fulltekstartikler fra det siste søket ble gjennomgått av Iversen. Etter fulltekstgjennomgangen ble 140 artikler ekskludert etter diskusjon i arbeidsgruppen. Data fra begge søkerne ble sammenfattet og analysert. Relevante predefinerte variabler fra protokollen for prosjektet ble registrert. Til sammen 844 relevante artikler i nordisk traumeforskning blir beskrevet i denne oppgaven (Vedlegg 2).



Figur 1. Databasesøk 1 og 2, sammenslått.

Etiske eller personvernmessige hensyn var ikke aktuelt i dette prosjektet.

3.1 Analyseverktøy

Det nettbaserte analyseprogrammet Covidence (1) ble benyttet for screening av artikler. Referansehåndteringsprogrammet EndNote X7 ble benyttet for å håndtere referansene. Variablene ble registrert i regnearket Excel fra Microsoft og analysene utført i Statistical Package for the Social Sciences (SPSS, IBM) versjon 24.

3.2 Inklusjonskriterier

Publisert forskning på alvorlige traumer, herunder epidemiologi og pasientbehandling gjennomført i de nordiske landene i tidsrommet 1995 og opp til søkets dato.

Publikasjoner utgitt på de nordiske språk eller engelsk ble inkludert. Pasienter i alle aldre ble inkludert.

Beskrivelse av alle nivåer i traumebehandlingen og traumesystemer. Alle tidsintervaller fra skadetidspunkt til ferdig rehabilitering. Studier på system- og fagutvikling.

3.3 Eksklusjonskriterier

Studier på iatrogene skader og skader med lav alvorlighetsgrad. Lav alvorlighetsgrad er i denne sammenhengen definert som skader som ikke fører til sykehusinnleggelse.

Laboratoriestudier som ikke involverer pasienter. Studier på alvorlige traumer i ikke-nordiske land utført av nordiske forskere.

3.4 Variabler

Fra hver inkludert referanse ble det hentet ut fem ulike hovedvariabler.

Årstall: Når de enkelte artiklene ble publisert.

Land: Hvilket nordisk land forskningen utgår fra.

Behandlingskjede: Hvilke deler av behandlingskjeden som er omtalt.

Type skade: Traumatologi omfatter potensielt alle mulige skader. Vi ønsket å beskrive alvorlige skadetyper og skademekanismer.

Forskningsdesign: Studiedesign i de inkluderte referansene.

3.4.1 Behandlingskjedevariabler

En behandlingskjede i traumatologien er hele kjeden av behandler og systemer for å ivareta den tilskadekomne pasient. Behandlingskjeden initieres av varsling, via prehospital behandling, intrahospital behandling og til slutt rehabilitering.

Vi har valgt å inkludere variabelen epidemiologi under "behandlingskjede" fordi mye av den epidemiologiske forskningen tar utgangspunkt i hele eller deler av den traumatologiske behandlingskjeden. Epidemiologiske studier er viktig for å beskrive trender, samt bestemme insidens og prevalens innenfor det traumatologiske fagfelt.

Prehospital behandling er definert som den delen av det profesjonelle helsetjenestetilbudet som omfatter alt som gjøres før pasienten ankommer sykehuset.

Akuttmottak og traumemottak er definert som den helsehjelp som utføres i mottak av den skadde pasienten, livsnødvendige akutte tiltak, innledende diagnostikk og bestemmelse av det videre behandlingsforløpet.

Kirurgisk behandling omfatter kirurgisk utredning og behandling av pasienten etter at den innledende undersøkelsen og tiltak er utført i akuttmottak/traumemottak.

Intensivbehandling omfatter utredning, diagnostikk og behandling som foregår på intensivavdeling etter at innledende behandling i akuttmottak og eventuelt kirurgiske tiltak er gjennomført.

Tidlig rehabilitering er definert som rehabilitering iverksatt under 3 måneder etter skadetidspunktet. Således omfattes også såkalt akutt rehabilitering som iverksettes allerede i den akutte fasen for å bedre prognosene for god funksjon.

Sen rehabilitering er definert som rehabilitering som utføres over 3 måneder etter skadetidspunkt.

Traumesystemer omfatter forskning utført på de overordnede systemer for ivaretakelse og integrering av systemer som skal sikre best mulig ivaretakelse av den hardt skadde pasient.

Forebyggende behandling omfatter forskning som tar sikte på å redusere hyppigheten av alvorlig skade, forebyggende tiltak og risikoanalyser.

Registerkvalitet og skåringssystemer omfatter forskning på ulike måter å klassifisere og registrere traumer og skademekanismer på. Det omfatter også forskning på systemer for å skåre alvorliggradsgrad eller diagnostiske skåringsskjema.

Diagnostikk omfatter diagnostikk av alvorlig skadde pasienter, herunder diagnostiske prosedyrer og diagnostiske tester.

Teamtrening omfatter forskning på trening og simuleringsstrening angående håndtering av traumepasienter eller prosedyrer.

Behandling på ordinær sengepost omfatter forskning på alvorlige skadde pasienter etter at pasienten er overført til ordinær sengepost for videre utredning og behandling.

3.4.2 Skadevariabler

Fleire samtidige alvorlige skader omfatter flere ulike skadetyper hos forskjellige pasienter, til forskjell fra multitraume der samme pasient har samtidige skader i flere organsystemer.

Hodeskade defineres som alvorlige hodeskader som følge av et traume.

Multitraume omfatter flere alvorlige samtidige skader i flere organsystemer hos samme pasient.

Ryggmargskade omfatter alvorlige spinale skader som følge av traume hos samme pasient.

Thoraxskade omfatter alvorlige skader i brystregionen hos samme pasient.

Abdominalskade omfatter alvorlige skader i abdomen hos samme pasient, som følge av stumpt eller penetrerende traume.

Ekstremitetskade omfatter alvorlige skader i over- eller underekstremitten hos samme pasient som følge av traume.

Aksidentell hypotermi omfatter alvorlig livstruende nedkjøling som følgetilstand til alvorlig skade.

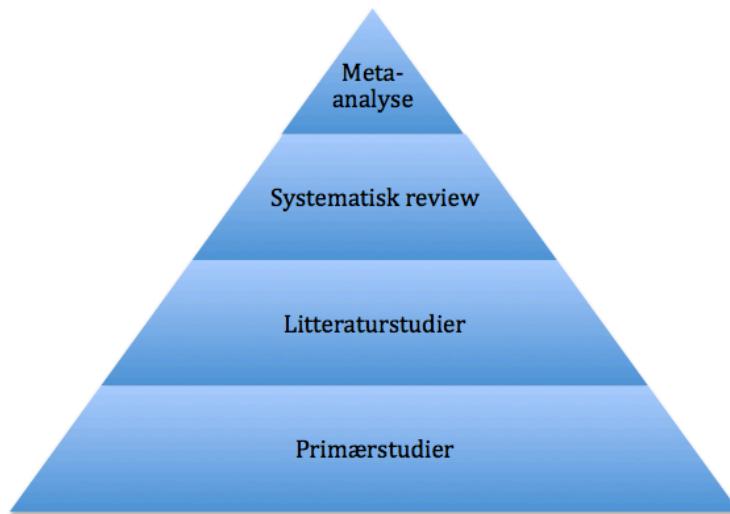
Nakke- og halsskader omfatter alvorlig skade i nakke- og halsregionen som følge av stumpt eller penetrerende traume hos samme pasient.

Bekkenskade omfatter alvorlige skader i bekkenregionen som følge av traume hos samme pasient.

Ikke definert skadetype inkluderer de artiklene hvor det ikke er redegjort spesifikt for hvilken skadetype som omtales i artikkelen.

3.4.3 Studiedesignvariabler

Studiedesignet i hver artikkel ble registrert og variablene ble kategorisert i henhold til kunnskapspyramiden (Figur 2) og evidenspyramiden (Figur 3) i henhold til definisjoner i studieprotokollen.

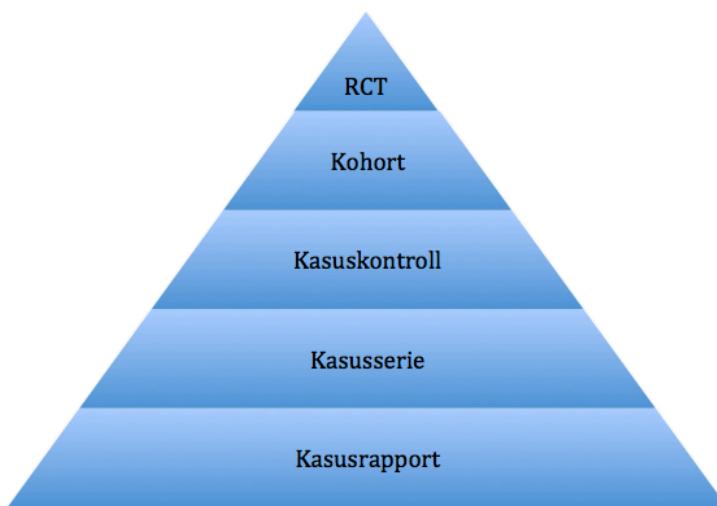


Figur 2. Kunnskapspyramiden.

Metaanalyse er et studiedesign med høyt evidensnivå som ved bruk av statistiske metoder sammenholder resultatene fra flere kvalitetssikrede forskningsarbeider innenfor samme tema for å gi svar på en problemstilling.

Systematisk review er et studiedesign som gjennom systematisert litteratursøk implementerer all tilgjengelig forskning av høy kvalitet innenfor et gitt område for å svare på et forskningsspørsmål.

Litteraturstudie er et studiedesign som gjennom ikke-strukturert søk implementerer tilgjengelig kunnskap fra enkeltstudier innenfor et gitt område for å svare på en vitenskapelig problemstilling.



Figur 3. Evidenspyramiden.

Randomisert kontrollert studie er gullstandard blant enkeltartikler. Randomisering av grupper unngår systematisk bias i fordeling av grupper, for eksempel ved utprøving av nye behandlingsformer.

Kohortstudie er studiedesign som følger en gruppe pasienter med felles eksposisjon. I denne typen forskning kan man svare på "hvordan går det med pasientene".

Kasuskontroll studie er studier der populasjonen er definert av utfallet.

Kasus serie eller pasientserier følger en gruppe pasienter uten andre grupper til sammenligning for å se hvordan det går med pasientene.

Kasus rapport er oftest representert av enkeltstående rapporter for eksempel knyttet til uvanlige diagnoser eller problemstillinger, samt eventuelt effekt av uvanlig behandling.

3.5 Statistiske metoder

Det er i all hovedsak utført deskriptiv analyse av dataene i datamaterialet. Ved hjelp av statistikkprogrammet SPSS er det kjørt deskriptiv analyse for antall for hver variabel med prosentutregning.

For enkelte data er det benyttet krysstabell utformet i SPSS for å sammenligne "behandlingskjede" og "skadetype". Av krysstabellen får man beskrevet antall i hver celle med prosentfordeling for å fastslå sammenheng mellom forskning på "behandlingskjede" og "skadetype".

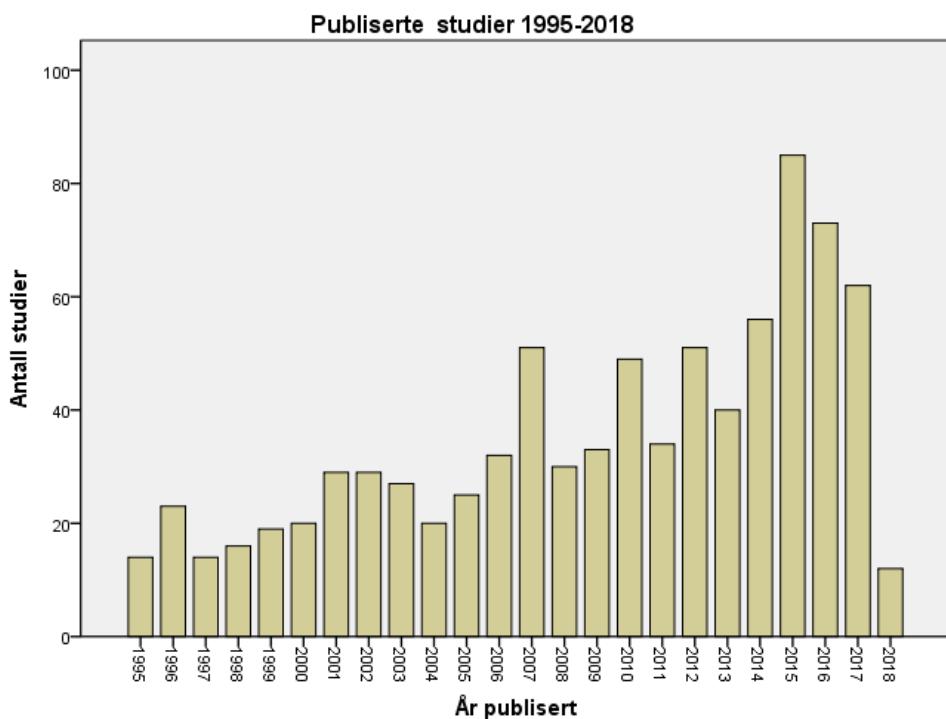
4 Resultater

Det er i observasjonsperioden registrert en jevn årlig økning i antall artikler som er publisert innenfor fagområdet traumatologi. Fordelingen i antall publikasjoner er relativt lik mellom Norge, Sverige og Danmark. Finland har færre publikasjoner sammenlignet med de andre nordiske landene, og Island har aller færrest publikasjoner i observasjonsperioden.

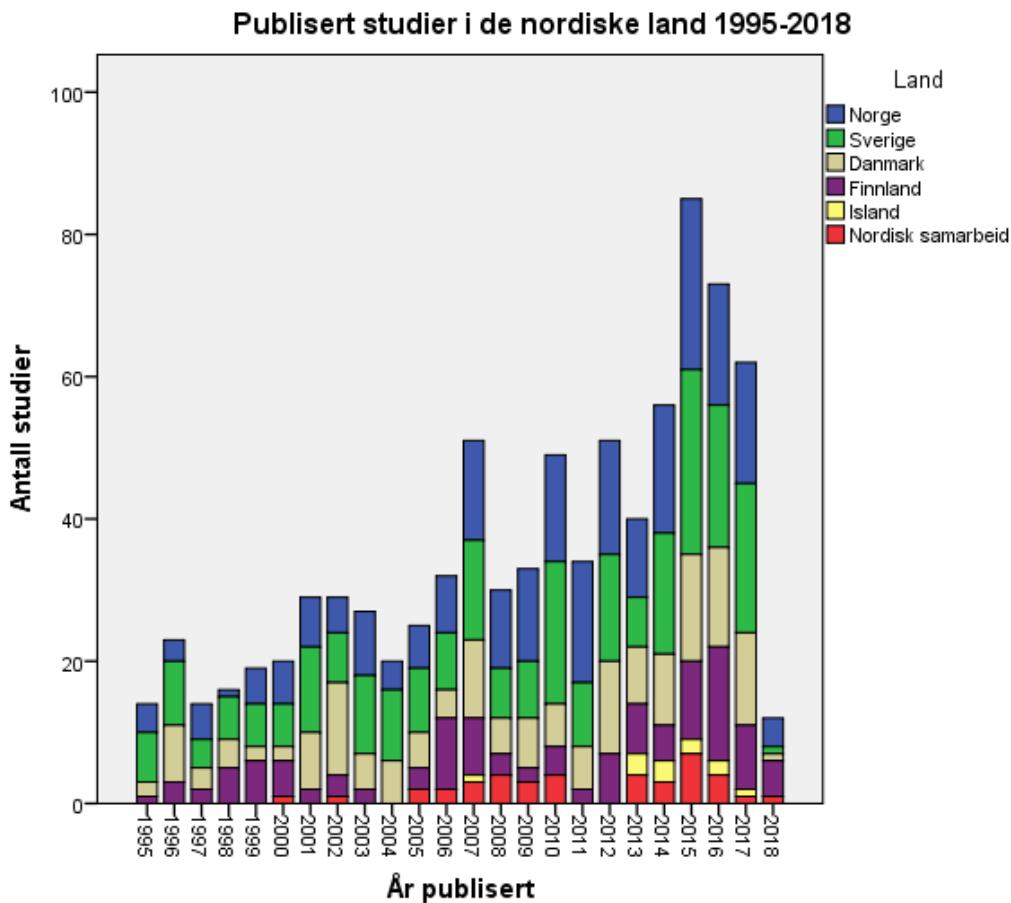
Det ses en overvekt av kohort-studier i materialet (61%). Det er kun registrert 2% studier av RCT type i materialet. Studier av behandlingskjeder var dominert av arbeider med epidemiologisk fokus (43%). Hypotesen om at fagområdet domineres av forskning på prehospital fase kan ikke bekreftes da antallet kun utgjorde 16%. Likevel er dette omtrent tre ganger mer enn forskning på andre ledd i behandlingskjeden innenfor traumatologien.

4.1 Antall artikler

Det ble i perioden 1995 til mars 2018 publisert 844 artikler som direkte adresserer det traumatologiske fagområdet. Figur 4 viser fordelingen av artikler publisert i perioden sortert på år.



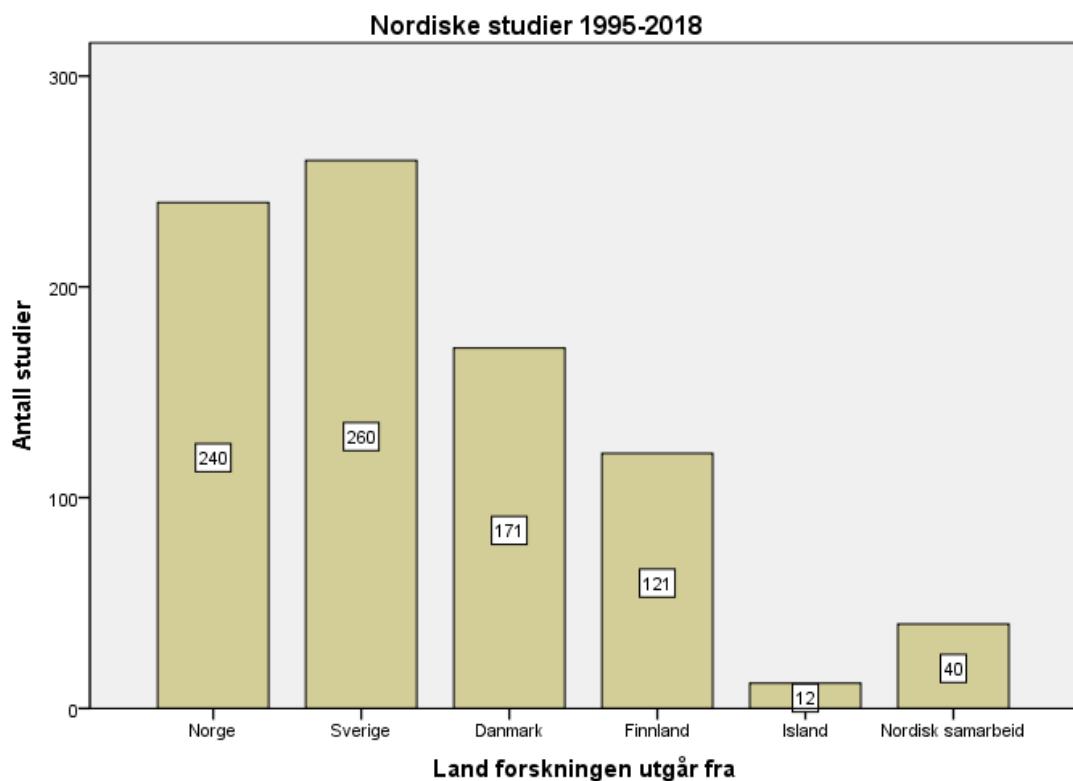
Figur 4. Publiserte studier innenfor området traumatologi i Norden i perioden 1995-2018



Figur 4b. Publiserte studier innenfor traumatologi i Norden i perioden 1995-2008, fordelt på de enkelte land

4.2 Fordeling mellom land

Det ble publisert flest artikler i Norge og Sverige i perioden. Figur 5 viser antall artikler produsert i de nordiske landene, og antall artikler basert på samarbeid mellom de nordiske landene, uten at andre nasjoner er involvert.



Figur 5. Publiserte studier i de nordiske landene i perioden 1995-2018

4.3 Behandlingskjede

I observasjonsperioden ble det publisert flest studier innenfor området epidemiologi med 365 (43,2%) artikler. Prehospital forskning dominerer deretter materialet med 136 (16,1 %) publiserte studier som spesifikt omtaler den prehospitale fasen. De øvrige ledd i behandlingskjeden representerer omrent 5% av materialet hver, mens traumesystemer og registre ligger enda lavere, ned mot 3% (Tabell 1).

Behandlingskjede beskrevet	Antall artikler N (%)
Epidemiologi	365 (43,2)
Prehospital behandling	136 (16,1)
Akuttmottak og traumemottak	48 (5,7)
Kirurgisk behandling	48 (5,7)
Intensivbehandling	44 (5,2)
Sen rehabilitering	42 (5,0)
Tidlig rehabilitering	34 (4,0)
Traumesystemer	32 (3,8)
Forebyggende behandling	31 (3,7)
Registerkvalitet og skåringssystemer	27 (3,2)
Diagnostikk	26 (3,1)
Teamtrening	7 (0,8)
Behandling ordinær sengepost	4 (0,5)
Total	844 (100)

Tabell 1. Antall artikler som beskriver ulike behandlingskjeder i traumatologisk forskning i de nordiske land i perioden 1995-2018.

4.4 Skadetyper

I kategorien skadetype ble det produsert flest artikler for kategorien som omfatter flere typer alvorlige skader hos ulike pasienter, således ikke "multitraume" som vil omfatte alvorlige skader i flere organsystemer hos samme pasient. Dernest er både multitraumatiserte pasienter og pasienter med alvorlig hodeskade beskrevet med henholdsvis 21,4% og 25,9%. De øvrige skadetyper er til dels mangelfullt beskrevet i den traumatologiske kontekst (Tabell 2).

Skadetype beskrevet	Antall artikler N (%)
Flere typer alvorlige skader	314 (37,2)
Hodeskade	219 (25,9)
Multitraume	181 (21,4)
Ryggmargskade	52 (6,2)
Thoraxskade	18 (2,1)
Abdominalskade	12 (1,4)
Ekstremitetskade	6 (0,7)
Aksidentell hypotermi	5 (0,6)
Nakke og halsskader	4 (0,5)
Bekkenskade	2 (0,2)
Ikke definert skadetype	31 (3,7)
Total	844 (100)

Tabell 2. Antall artikler som beskriver skadetyper i traumatologisk forskning i de nordiske land i perioden 1995-2018.

4.5 Sammenheng mellom skadetype og behandlingskjede

Tabell 3 viser sammenhengen mellom skadetyper og ledd i behandlingskjeden. Tabellen viser at hovedvekten av forskningen, uavhengig av ledd i behandlingskjeden, er utført på flere ulike alvorlige skader, multitraumer og hodeskader.

Skadetype/ Behandlingskjede	Forebyggende behandling	Prehospital behandling	Akuttmottak og traumemottak	Kirurgisk behandling	Intensiv- behandling	Sen rehabilitering	Tidlig rehabilitering	Traume- system	Epidemiologi	Registerkvalitet og skåringssystemer	Diagnostikk	Teamtrening	Behandling ordinær sengepost	Total
Fleire typer alvorlige skader	22 (71,0)	62 (45,6)	9 (18,8)	8 (16,7)	7 (15,9)	3 (7,1)	0	7(21,9)	180 (49,3)	10 (37,0)	2 (7,7)	0	4 (100,0)	314 (37,2)
Hodeskade	3 (9,7)	15 (11,0)	1 (2,1)	14 (29,2)	15 (34,1)	20 (47,6)	29 (85,3)	4 (12,5)	103 (28,2)	3 (11,1)	12 (46,2)	0	0	219 (25,9)
Multitraume	4 (12,9)	45 [33,1]	34 (70,8)	5 (10,4)	17 (38,6)	2 (4,8)	0	12 (37,5)	47 (12,9)	6 (22,2)	5 (19,2)	4 (57,1)	0	181 (21,4)
Ryggmargskade	0	0	0	1 (2,1)	1 (2,3)	15 (35,7)	5 (14,7)	2 (6,3)	20 (5,5)	6 (22,2)	2 (7,7)	0	0	52 (6,2)
Thoraxskade	0	1 (0,7)	1 (2,1)	6 (12,5)	0	0	0	1 (3,1)	7 (1,9)	0	2 (7,7)	0	0	18 (2,1)
Abdominalskade	0	0	0	8 (16,7)	0	0	0	0	2 (0,5)	0	1 (3,8)	1 (14,3)	0	12 (1,4)
Ekstremitetsskade	0	1 (0,7)	0	0	2 (4,8)	0	0	0	3 (0,8)	0	0	0	0	6 (0,7)
Aksidentell hypotermi	0	3 (2,2)	0	0	2 (4,5)	0	0	0	0	0	0	0	0	5 (0,6)
Nakke og halsskader	0	0	0	3 (6,3)	0	0	0	0	0	0	1 (3,8)	0	0	4 (0,5)
Bekkenskade	0	0	0	2 (4,2)	0	0	0	0	0	0	0	0	0	2 (0,2)
Ikke definert skadetype	2 (6,5)	9 (6,6)	3 (6,3)	1 (2,1)	2 (4,5)	0	0	6 (18,9)	3 (0,3)	2 (7,4)	1 (3,8)	2 (28,6)	0	31 (3,7)
Total	31 (100)	136 (100)	48 (100)	48 (100)	44 (100)	42 (100)	34 (100)	32 (100)	365 (100)	27 (100)	26 (100)	7 (100)	4 (100)	844 (100)

Tabell 3. Sammenheng mellom skadetype og behandlingskjede i traumeforskning.

4.6 Studiedesign brukt i Nordisk traumeforskning

I kategorien studiedesign sortert etter evidensnivå i henhold til klassifisering i henhold til kunnskapspyramide ser man at bare 19 (2,3 %) av alle identifiserte studier var av typen sekundærlitteratur. Dette betyr at det er lite forskning som er publisert som tilfredsstiller kravene til de høyeste evidensnivåene. Dette passer med den rådende oppfatning i fagmiljøet (Tabell 4).

Studiedesign	Antall artikler N (%)
Meta-analyse	1 (0,1)
Systematisk review	4 (0,5)
Litteraturstudier	14 (1,7)
Primærstudier	825 (97,7)
Total	844 (100)

Tabell 4. Studiedesign sekundærlitteratur i nordisk traumeforskning i perioden 1995-2018.

I kategorien studiedesign sortert etter evidensnivå i henhold til klassifisering i henhold til evidens-pyramiden ser man at bare 16 (2%) av studiene sorterer under det høyeste evidensnivået, randomisert kontrollert studie (Tabell 5).

Studiedesign sortert etter evidensnivå	Antall artikler N (%)
Randomisert kontrollert dobbeltblind studie	3 (0,4)
Randomisert kontrollert studie	13 (1,6)
Kohortstudie	505 (61,2)
Kasuskontroll studie	35 (4,2)
Kasus-serier	259 (31,4)
Kasus-rapport	10 (1,2)
Total	825 (100)

Tabell 5. Studiedesign primærlitteratur i nordisk traumeforskning i perioden 1995-2018.

4.7 Sammenheng mellom studiedesign og behandlingskjede

Studier over behandlingskjeder i traumatologien bruker i de fleste tilfeller kohortstudier og kasusserier. Randomisert kontrollert studie brukes primært for å beskrive behandlingsalternativer i tidlig rehabilitering etter traume (Tabell 6).

Behandlingskjede/ Studiedesign	Meta-analyse	Systematisk <u>review</u>	Litteratur-studie	Randomisert kontrollert studie	Kohort-studie	Kasuskontroll studie	Kasus serie	Kasus rapport	Total
Epidemiologi	0	1 (0,3)	0	2 (0,5)	272 (74,5)	23 (6,3)	65 (17,8)	2 (0,5)	365 (100,0)
Prehospital behandling	0	2 (1,5)	4 (2,9)	2 (1,5)	70 (51,5)	2 (1,5)	54 (39,7)	2 (1,5)	136 (100,0)
Akuttmottak og traumemottak	0	0	0	3 (6,3)	22 (45,8)	1 (2,1)	22 (45,8)	0	48 (100,0)
Kirurgisk behandling	0	1 (2,1)	2 (4,2)	0	33 (68,8)	1 (2,1)	10 (20,8)	1 (2,1)	48 (100,0)
Intensivbehandling	0	0	0	4 (9,1)	30 (68,2)	1 (2,3)	7 (15,9)	2 (4,5)	44 (100,0)
Sen rehabilitering	0	0	1 (2,4)	4 (9,5)	18 (42,9)	0	18 (42,9)	1 (2,4)	42 (100,0)
Tidlig rehabilitering	0	0	0	7 (20,6)	22 (64,7)	0	5 (14,7)	0	34 (100,0)
Traumesystemer	0	1 (3,1)	1 (3,1)	0	6 (18,8)	0	23 (71,9)	1 (3,1)	32 (100,0)
Forebyggende behandling	0	0	0	0	9 (29,0)	5 (16,1)	17 (54,8)	0	31 (100,0)
Registerkvalitet og skåringssystemer	0	0	1 (3,7)	1 (3,7)	3 (11,1)	0	22 (81,5)	0	27 (100,0)
Diagnostikk	1 (3,8)	0	4 (15,4)	0	18 (69,2)	2 (7,7)	1 (3,8)	0	26 (100,0)
Teamtrening	0	0	0	0	0	0	7 (100,0)	0	7 (100,0)
Behandling ordinær sengepost	0	0	0	0	1 (25,0)	0	13 (75,0)	0	4 (100,0)
Total	1 (0,1)	5 (0,6)	13 (1,5)	23 (2,7)	504 (59,7)	35 (4,1)	254 (30,1)	9 (1,1)	844 (100,0)

Tabell 6. Studiedesign i forskning på behandlingskjeder i nordisk traumeforskning.

4.8 Sammenheng mellom studiedesign og skadetyper

Studier over skadetyper i traumatologien bruker i de fleste tilfeller kohortstudier og kasusserier. Flest studier er utført på flere samtidige skader, hodeskade, multitraume og ryggmargsskade. Det er publisert få randomisert kontrollerte studier. Studiedesignet brukes primært for å beskrive behandlingsalternativer i håndteringen av hodeskade og ryggmargsskade (Tabell 7).

Skadetype/ Studiedesign	Meta- analyse	Systematisk review	Litteratur- studie	Randomisert kontrollert studie	Kohort- studie	Kasuskontroll studie	Kasus serie	Kasus rapport	Total
Flere typer alvorlige skader	0	1 (0,3)	2 (0,6)	3 (1,0)	175 (55,7)	21 (6,7)	110 (35,0)	2 (0,6)	314 (100,0)
Hodeskade	1 (0,5)	1 (0,5)	6 (2,7)	9 (4,1)	156 (71,2)	9 (4,1)	36 (16,4)	1 (0,5)	219 (100,0)
Multitraume	0	2 (1,1)	1 (0,6)	4 (2,2)	108 (59,7)	2 (1,1)	61 (33,7)	3 (1,7)	181 (100,0)
Ryggmargskade	0	0	1 (1,9)	5 (9,6)	27 (51,9)	1 (1,9)	17 (32,7)	1 (1,9)	52 (100,0)
Thoraxskade	0	0	1 (5,6)	0	13 (72,2)	2 (11,1)	2 (11,1)	0	18 (100,0)
Abdominalskade	0	1 (8,3)	0	0	9 (75,0)	0	2 (16,7)	0	12 (100,0)
Ekstremitetsskade	0	0	0	0	3 (50,0)	0	3 (50,0)	0	6 (100,0)
Aksidentell hypotermi	0	0	0	0	1 (20,0)	0	2 (40,0)	2 (40,0)	5 (100,0)
Nakke og halsskader	0	0	0	0	4 (100,0)	0	0	0	4 (100,0)
Bekkenskade	0	0	0	0	0	0	2 (100,0)	0	2 (100,0)
Ikke definert skadetype	0	0	2 (6,5)	2 (6,5)	8 (25,8)	0	19 (61,3)	0	31 (100,0)
Total	1 (0,1)	5 (0,6)	13 (1,5)	23 (2,7)	504 (59,7)	35 (4,1)	254 (30,1)	9 (1,1)	844 (100,0)

Tabell 7. Sammenheng mellom studiedesign og skadetyper i nordisk traumeforskning.

5 Diskusjon

Det har vært en gradvis økning i antall publiserte forskningsartikler på fagområdet traumatologi i observasjonsperioden. Dette tyder på at forskningsinnsatsen på området øker, noe som passer med inntrykket av det generelt økte fokuset på traumebehandling. Det har over de siste år blitt implementert flere nye systemer for å øke kvaliteten i behandlingen som gis, for eksempel traumeregisteret (21). Man kan sågar tenke seg at de nordiske land de siste tiårene i større grad enn tidligere har blitt utsatt for alvorlige hendelser, herunder også terrorismepregete hendelser (24). Slike hendelser får bred mediedekning og øker således sannsynligvis fokuset på systemene som skal ivareta skadde pasienter. Etter 22. juli-angrepet i Norge ble det gjort en omfattende gjennomgang av den helsemessige innsatsen (25), og slike hendelser kan gi opphav for økt fokus på forskning.

Bidrag mellom de nordiske landene er omtrent på samme nivå mellom Norge, Sverige og Danmark, mens Finland og spesielt Island genererer lite publikasjon. Våre data tyder på at det per million innbyggere utføres mest traumeforskning i Norge.

Innenfor fagområdet traumatologi publiseres det relativt få RCT, men mange kohortstudier og kasusserier. På grunn av den tradisjonelle måten å vurdere evidensnivå på oppfattes dette som at traumatologien generelt produserer forskning av lavere kvalitet. Som en konsekvens av dette blir også få systematic reviews og meta-analyser publisert, da primærstudier av høy kvalitet ikke foreligger.

Innenfor alle ledd i behandlingskjeden forskes det på få skadetyper, hovedsakelig på pasienter med ulike alvorlige skader, multitraume og hodeskader. Det produseres lite forskning på spesifiserte skader for eksempel i bryst, buk og ekstremiteter. Det er utført relativt lite forskning på rehabilitering og forebyggende arbeid. Det er utført relativt mange epidemiologiske studier, i hovedsak med utgangspunkt i data fra ulike registerkilder, for eksempel traumeregisteret, men også fra andre typer skaderegistre. Tiltak som traumeregisteret (21) gir opphav til data som tidligere har vært vanskelig tilgjengelig for forskere. Datainnsamling i traumesammenheng er krevende, og økt tilgang på datamateriale vil gjøre gjennomføringen av forskningsprosjekter betydelig enklere.

I resultatdelen framgår det at 314 (37,2 %) av samtlige inkluderte artikler er kategorisert som såkalt "flere typer alvorlige skader". Dette er studier som ikke beskriver de enkelte skadetypene spesielt, men diskuterer de mer overordnede aspektene vedrørende traumebehandling. Dette vil omfatte arbeider som tar for seg traumesystemer, varslingsssystemer, registre, konseptutvikling og kvalitetskontroll. I disse arbeidene er det ikke nødvendigvis av interesse å differensiere skadetype nærmere. Arbeidene omfatter ofte flere pasienter med ulike skader, således kan det ikke defineres som multitraumer. Disse arbeidene er viktige for å kartlegge og evaluere den pågående innsatsen som gjøres på fagområdet traumatologi. Mange av de epidemiologiske studiene sammenfatter flere skadetyper/hendelser som sorterer innenfor for eksempel samme behandlingsledd. Disse studiene er helt sentrale for å drive de overordnede traumesystemene framover, til forskjell fra enkeltstudier som tar opp mer konkrete behandlingsmessige aspekter. Begge deler er svært viktige for at fagfeltet som helhet gradvis skal bli bedre, for pasientens beste.

I tillegg til dette skiller multitraumer og hodeskader seg ut som områder det forskes mest på. Dette er naturlig all den tid den multitraumatiserte pasienten representerer den "klassiske" traumepasienten. Man burde kunne forvente at en stor andel av

forskning retter seg nettopp mot multitraumer, siden disse skadene representerer utfordringer i diagnostikk og behandling da man har flere samtidige tilstader som må håndteres i riktig rekkefølge. Det er av vesentlig betydning for det traumatologiske fagområdet at forskning på denne pasientgruppen er tilstrekkelig beskrevet.

Hodeskader er beskrevet i omtrent samme omfang som multitraumer. Dette er interessant i den forstand at det er den isolerte spesifiserte skadetypen i særdeleshet som er mest omtalt i litteraturen. En mulig forklaring vil være at det i prinsippet er to fagmiljøer som beskriver disse skadene. Både traumatologien og nevrokirurgien har alvorlig hodeskade som en viktig tilstand innenfor sine arbeidsområder. Man kan tenke seg at de nevrokirurgiske fagmiljøene har lang erfaring med forskning på hodeskader, og at dette således også vil gjenspeiles i traumeforskningen.

Randomiserte kontrollerte studier, såkalte RCT-studier, representerer gullstandarden hva angår forskningsdesign. Formålet er å kontrollere om et tiltak har effekt, vanligvis ved å sammenligne to ulike grupper som randomiseres til en av to mulige behandlinger. Det stilles krav til selve randomiseringen, for å redusere risiko for feilkilder. Dette er et svært godt forskningsdesign i mange studier der man har mulighet til å sammenligne to behandlinger, eller sågar placebo. I traumesammenheng er forholdene annerledes, og det vil være svært betenklig å randomisere pasientene til den ene eller andre typen behandling i den akutte fasen. Det finnes som nevnt innarbeidete rutiner for håndtering av tilskadekomne, og det vil være etisk uforsvarlig å fravike disse prinsippene for mye. Man kunne tenke seg å sette opp en RCT for å sammenligne to ulike behandlinger, men da måtte den forventede effekten ligge svært tett opp mot hverandre. Dette er tradisjonelt sett ikke like interessant for de som skal finansiere og gjennomføre studiene, da det ikke tilfører vesentlig ny kunnskap. I tillegg ville man måtte ha hatt et tilstrekkelig stort materiale og like eller sammenlignbare pasienter. Dette er ikke enkelt gjennomførbart på det traumatologiske fagområdet. For å sette eksempelet på spissen ville det være svært kritikkverdig å randomisere en gruppe traumepasienter til å gjennomgå standard akutt computer-tomografisk bildeundersøkelse (Traume-CT), mens den andre gruppen ikke tilbys bildeundersøkelser. For noen år siden ble det gjennomført en mye omtalt RCT i Norge, det såkalte "hjertelotteriet" (26). Ved akutt hjertestans utenfor sykehus har det i flere år vært standard prosedyre å administrere 1 mg adrenalin intravenøst under pågående gjenoppliving. Det har i mange

laboratoriestudier vært antydet at adrenalin ikke endrer langtidsoverlevelsen. Således ble det stilt spørsmålstege ved om det var forsvarlig å bruke kostbare sekunder på og administrere dette medikamentet med tvilsom effekt. Løsningen ble en randomisert kontrollert studie, der ambulanseenheter som rykket ut på hjertestans åpnet en konvolutt på vei ut der det var angitt om det skulle administreres adrenalin under dette oppdraget eller ikke. Studien viste ingen forskjell i overlevelse på de som hadde fått adrenalin eller ikke, men studien fikk mye kritikk for å "gamble" med overlevelsen til pasienter med hjertestans (26).

Et stort overtall av arbeider som er utført i traumeforskningen er såkalte kohort-studier. Blant annet har kohort-studier vært sentrale i forskning på blodtransfusjon hos alvorlig skadde pasienter (27), samt bruk av væskebasert resuscitering utenfor sykehus (28). Av studiedesign er det ikke overraskende at kohort-studier er dominerende. Det viktigste spørsmålet en kohort kan besvare er "Hva er effekten av denne eksponeringen?". Tradisjonelt sett betyr dette at kohorter er omfattende og langvarige prosjekter, da man følger en gruppe over tid. Det er intet påfyll i studiepopulasjonen underveis, selv om pasienter dør, går ut av forskningen eller forsvinner. Man ser at varianter av kohort-studier brukes mye i traumeforskning, der selve skaden er utgangspunktet og den felles eksponeringen. Observasjonstiden starter gjerne ved skadetidspunktet, og pasientene følges gjennom pasientforløpet. Slik kan man måle effekt av tiltak underveis sett opp mot for eksempel overlevelse eller funksjon. Dette er et studiedesign man kan forstå er attraktivt i traumeforskning, siden prosjektene starter samtidig som skaden skjer. Dette kan eksempelvis gjøres i praksis ved gjennomgang av journaler fra traumemottak, der man ser på ulike parametere. Et aktuelt eksempel kan være tid fra innkomst til aktuelle røntgenundersøkelser er gjennomført. Dette er lett målbare størrelser i all den tid det allerede finnes innarbeidede rutiner for utfylling av logg ved mottak av en hardt skadet pasient. Det samme kan overføres til alle deler av behandlingskjeden der helt konkrete data genereres gjennom journalskriving, logg/historikk i AMK etc. Vanskeligere målbare størrelser vil være ting som kommunikasjon, samarbeid og pasientopplevelser. Det vil også være vanskelig å vurdere om medlemmene i traumeteamet sine vurderinger er riktige, eller kunne vært gjort annerledes, da den aktuelle situasjonsforståelsen vanskelig kan måles eller kontrolleres. I nasjonal traumeplan anbefales det videooppptak av traumemottak (3). Dette har også BEST-stiftelsen praktisert under trening i mange

år. Deltakerne på deres kurs beskriver nytten av å evaluere egen innsats som stor. Her kan det ligge godt materiale for forskning på oppreten og beslutningstaking i den akutte, vanskelige målbare, fasen i et traumemottak.

5.1 Finansiering av traumeforskning i Norden

Det har i arbeidet med artiklene vist seg svært vanskelig å påvise hvilken finansiering som ligger bak arbeidene som er utført. I det vesentlige blir det kommentert eventuelle interessekonflikter som eventuelt måtte foreligge hos forfatterne. Artiklene angir sjeldent hvordan de økonomiske aspektene i prosjektene er ivaretatt. Et av spørsmålene man ønsket å besvare var hvordan forskningen er finansiert, for dermed å kunne påvise sammenheng mellom eventuell egeninteresse i fagfeltet og forskningsspørsmålene som blir stilt.

En av hypotesene forut for prosjektet var at det kunne være en sammenheng mellom hvem som finansierer forskningen og hvorvidt konklusjonene gagner deres interesser. Man kan tenke seg at dette kunne bidra til en skjevfordeling av fokus i arbeidene i en retning som gagner oppdragsgiver.

Det er uheldig hvis finansiering av forskning styrer hvor fokuset rettes. Man kan tenke seg at store aktører innenfor deler av behandlingskjeden står sterkere for å initiere prosjekter, som naturlig nok vil omhandle deres egne forskningsinteresser. Dette fører i sin tur til mindre fokus på deler av behandlingskjeden som ikke oppfattes like "atraktiv" å undersøke nærmere.

Spørsmålet om finansiering av studiene kan således ikke beskrives i denne oppgaven, noe som oppfattes som et funn i seg selv.

5.2 Sterke sider ved oppgaven

Søket er gjort i relevante databaser, og søkeret er utformet i samarbeid med erfaren bibliotekar ansatt ved Universitetsbiblioteket. Alle referansene er vurdert av to uavhengige medarbeidere. Prosjektet evaluerer forskning som er utført over et langt tidsrom, således stor observasjonstid som inkluderer alt som er gjort av traumeforskning i Norden i perioden. Prosjektgruppen består av medlemmer som kjenner forskningsfeltet svært godt gjennom sitt daglige virke.

5.3 Svake sider ved oppgaven

Datamaterialet er håndert ut fra fastsatte inklusjons- og eksklusjonskriterier, men screeningen er utført av flere personer. Screeningen av det første søket er utført av Hansen og Jeppesen, mens screeningen av det siste søkeret er utført av Iversen og Jeppesen. Registrering av variabler er utført av Hansen og Iversen. Dette kan gi opphav til små variasjoner i vurderingen av referansene.

Det har ikke vært mulig å fremskaffe samtlige artikler søkeret returnerte for vurdering. Etter omfattende søk i tilgjengelige nettressurser, universitetsbibliotekene og nasjonalbiblioteket ble artikler det ikke var mulig å vurdere i fulltekst ekskludert.

Søkestrenge (vedlegg 1) kan være en begrensende faktor for hvilke arbeider som blir fanget opp av søkeret. Fagområdet er stort, og det er mulig at et enda bredere søkeret hadde ført til inklusjon av flere referanser.

6 Konklusjon

Det er i observasjonsperioden registrert en jevn årlig økning i antall artikler som er publisert på fagområdet traumatologi. Fordelingen i antall publikasjoner er relativt lik mellom Norge, Sverige og Danmark. Finland har færre publikasjoner sammenlignet med de andre nordiske landene, og Island har aller færrest publikasjoner.

Det ses en overvekt av kohort-studier i materialet (61%). Det er kun registrert 2% studier av RCT type i materialet. Studier av behandlingskjeder var dominert av arbeider med epidemiologisk fokus (43%). Hypotesen om at fagområdet domineres av forskning på prehospital fase kan ikke bekreftes da antallet kun utgjorde 16%. Likevel er dette omtrent tre ganger mer enn forskning på andre ledd i behandlingskjeden innenfor traumatologien.

Oppgaven har pekt ut områder innenfor traumatologien som er mangelfullt beskrevet. Dette dreier seg i hovedsak om forskning på isolerte alvorlige skader i traumesammenheng. Det vil være av interesse å vite mer om disse skadetypene i traumatologisk sammenheng for å sikre at diagnostikk og behandling gjøres i henhold til evidensbasert praksis. Det er utført lite forskning på traumepasienter etter den akutte fasen, der pasienten er overført til ordinær sengepost. Fra klinisk praksis vet man at

dette skjer på de fleste sykehus, da de færreste innehar egen sengepost for traumatologiske pasienter. Det er nærliggende å tro at det koordinerte, fokuserte og samordnede fokuset på traumepasienten svekkes når pasienten knyttes til en spesiell avdeling. I traumeteam har ortopeder en sentral plass, da mange traumer medfører skjelettskader som skal behandles. Det er identifisert lite forskning på ortopediske problemstillinger i traumatologisk sammenheng.

Det vil også være av interesse å sammenholde resultatene fra prosjektet med et tilsvarende prosjekt for eksempel med materiale fra europeisk traumeforskning. Materialet i denne oppgaven knytter seg utelukkende til nordiske publikasjoner, og det er mulig at områdene som er mangelfullt beskrevet i denne gjennomgangen dekkes opp av internasjonal forskning der også overføringsverdien til nordiske forhold er god.

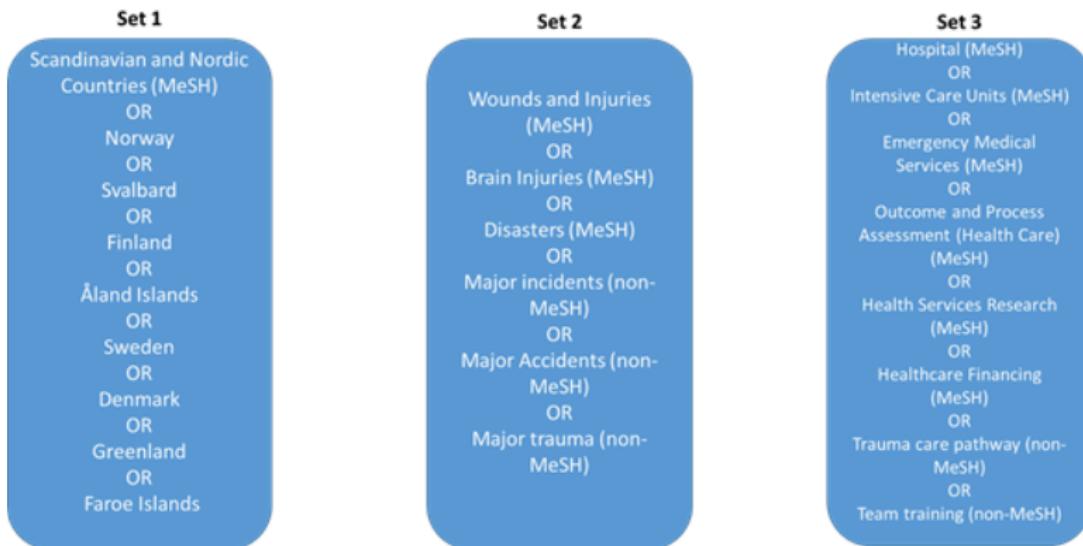
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8 Vedlegg

8.1 Vedlegg 1 – Søkestreng



Vedlegg 1. Søkestreng for systematisk litteratursøk felles for søker 1 & 2.

8.2 Vedlegg 2 – Komplett referanseliste for inkluderte artikler

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8.3 Vedlegg 3 – GRADE vurdering av fem RCT fra prosjektet

<p>Referanse: Nils Berginstra ïm, MSc; Peter Nordstro ïm, PhD; Robert Schuit, BSc; Anna Nordstro ïm, PhD. The Effects of (-)-OSU6162 on Chronic Fatigue in Patients With Traumatic Brain Injury: A Randomized Controlled Trial. <i>J Head Trauma Rehabil</i> Vol. 32, No. 2, pp. E46–E54</p>		Studiedesign: RCT	
		Grade - kvalitet	1b
Formål	Materiale og metode	Resultater	Diskusjon/kommentarer/sjekkliste
To examine the effects of the monoaminergic stabilizer (-)-OSU6162 on mental fatigue in patients with traumatic brain injury	<p>Rekruttering deltakere (randomisering) Randomization to the (-)-OSU6162 and placebo treatment groups was performed externally to ensure blinding of participants and assessors using a permuted-block design with a block size of 10.</p> <p>Inclusion criteria: TBI more than 12 months previously; age 18 to 65 years; moderate disability or better recovery (ie, Extended Glasgow Outcome Scale score >5); and self-experienced fatigue, defined as a Fatigue Severity Scale score of more than 36.</p> <p>Exclusion criteria: Other neurological disease or severe psychiatric condition; severe dementia; alcohol or drug abuse; heart, liver, kidney, or active neoplastic disease; personal or immediate family member's history of seizures; and other surgical or medical conditions that might have interfered with active treatment. ECT therapy within the previous 90 days and those taking clozapine or other drugs capable of inducing hepatic enzyme metabolism. Pregnant women and women of childbearing age who were not using contraceptives.</p> <p>Outcome: Self-assessment scales. Secondary: Neuropsychological measures.</p> <p>Eksponeringsvariabler (validert/ikke validert) New treatment or placebo.</p> <p>Viktige konfunderende faktorer Not reported</p> <p>Statistiske metoder Student t-test. Chi-squared test. Paired sample t-test. Linear regression. Intention to treat analysis.</p>	<p>Hovedfunn No difference between groups on any scale was detected at baseline. During follow-up, both groups showed significant improvement on the Fatigue Severity Scale, Mental Fatigue Scale, and Rivermead Post-Concussion Symptoms Questionnaire (all $P < .01$). The treatment group also showed significant improvement on the Hospital Anxiety and Depression Scale ($P = .03$). However, initial unadjusted analyses showed no difference between groups in change on any scale during follow-up.</p> <p>Bifunn No significant difference between groups was detected for any neuropsychological measure at baseline. Both groups showed significant improvement on the Coding, Paced Auditory Serial Addition Test, and IVA Auditory Prudence during follow-up (all $P < .05$). However, no significant difference between the control and treatment groups was found during follow-up (all $P > .05$).</p>	<p>Sjekkliste:</p> <ul style="list-style-type: none"> • Er formålet med studien klart formulert? Ja • Ble utvalget fordelt til de ulike gruppene med randomiseringsprosedyre? Ja • Ble alle deltagarne gjort rede for på slutten av studien? Ja • Ble deltakere/studiepersonell blindet mht gruppelihørighet? Ja • Var gruppene like ved starten? Ja • Ble gruppene behandlet likt? Ja, foruten intervensjonen • Hva er resultatene? Ingen effekt av ny behandling • Kan resultatene overføres til praksis. Noe begrenset grunnet lavt antall inkluderte. • Ble alle utfallsmål vurdert? Ja • Er fordelene verdt ulemper/kostnader? Ingen fordele rapportert <p>Hva diskuterer forfatterne om:</p> <p>Styrke Ikke direkte diskutert.</p> <p>Svakhet Lite antall inkluderte. Noe uklare inklusjonskriterier. Viser forfatterne til annen litteratur som styrker/svekker resultatene? Ja, relevante artikler diskutes.</p> <p>Har resultatene plausible biologiske forklaringer? Ja, basert på funn i andre refererte prosjekter kan biologiske mekanismer bak hypotesen forklares.</p>
Konklusjon	Treatment with (-)-OSU6162 had no significant effect on mental fatigue in patients with traumatic brain injury compared with placebo.		
Land	Sweden		
År data innsamling	Between April 2013 and June 2014		

<p>Referanse: Jensen JF, Egerod I, Bestle MH, Christensen DF, Elklit A, Hansen RL, et al. A recovery program to improve quality of life, sense of coherence and psychological health in ICU survivors: a multicenter randomized controlled trial, the RAPIT study. Intensive Care Medicine. 2016;42(11):1733-43.</p>			Studiedesign: RCT
			Grade - kvalitet 1b
Formål To test the effectiveness of a post-ICU recovery program compared to standard care during the first year after ICU discharge	Materiale og metode Rekruttering deltakere (randomisering) Patients were randomly assigned in a 1:1 ratio to receive SC plus the recovery program or SC alone. Konklusjon The tested recovery program was not superior to standard care during the first 12 months post-ICU.	Resultater Hovedfunn No statistically difference was observed in primary or secondary outcome measurements at 3 and 12 months.	Diskusjon/kommentarer/sjekkliste Sjekkliste: <ul style="list-style-type: none"> • Er formålet med studien klart formulert? Ja. • Ble utvalget fordelt til de ulike gruppene med randomiseringsprosedyre? Ja. • Ble alle deltakerne gjort rede for på slutten av studien? Ja. • Ble deltakere/studiepersonell blindet mht gruppetilhørighet? Nei • Var gruppene like ved starten? Ja. • Ble gruppene behandlet likt? Ulik intervensjon • Hva er resultatene? Ingen forskjell mellom intervensjonene • Kan resultatene overføres til praksis? Ja. • Ble alle utfallsmål vurdert? Alle relevante • Er fordelene verdt ulemper/kostnader? Det vises ikke forskjeller i prosjektet. Hva diskuterer forfatterne om: <p>Styrke Multisenter design. Streng protokoll. Spesialtrente medarbeidere.</p> <p>Svakhet Rekruttert for syke pasienter. Risiko for at ikke alle symptomer fanges opp.</p> <p>Viser forfatterne til annen litteratur som styrker/svekker resultatene? Ja, til andre relevante studier i andre land.</p> <p>Har resultatene plausible biologiske forklaringer? Ja</p>
Land Denmark	År data innsamling December 2012 – December 2015.		

<p>Referanse: Nichol A, French C, Little L, Haddad S, Presneill J, Arabi Y, et al. Erythropoietin in traumatic brain injury (EPO-TBI): a double-blind randomised controlled trial. The Lancet. 2015;386(10012):2499-506.</p>			Studiedesign: RCT
			Grade - kvalitet 1b
Formål	Materiale og metode	Resultater	Diskusjon/kommentarer/sjekkliste
The aim of the study was to ascertain whether or not the administration of erythropoietin compared with placebo improves neurological outcome at 6 months after injury in patients with moderate or severe traumatic brain injury.	<p>Rekruttering deltakere (randomisering) 606 patients were enrolled and randomly assigned to erythropoietin (n=308) or placebo (n=298).</p> <p>Inclusion criteria: Less than 24 h since traumatic brain injury, anticipated intensive care length of stay at least 48 h, a haemoglobin concentration not exceeding the upper limit of normal at each enrolling institution and provision of valid consent.</p> <p>Exclusion criteria: A GCS of 3 and fixed dilated pupils; history of deep vein thrombosis, pulmonary embolism, or other thromboembolic event; treatment with erythropoietin in the past 30 days; and the first dose of study drug unable to be given within 24 h of primary injury.</p> <p>Outcome: The primary outcome at 6 months was the patients neurological status. Secondary outcomes were proportional odds model of neurological outcome, and mortality assessed at 6 months, prox deep venous thrombosis detected by ultrasound, and occurrence of a composite thrombotic outcome according to previously published definitions.</p> <p>Eksponeringsvariabler (validert/ikke validert) Validated administration of erythropoietin or saline solution according to randomised groups.</p> <p>Viktige konfunderende faktorer Not reported.</p> <p>Statistiske metoder Fishers exact test. Interim analysis. Modified intention-to-treat approach.</p>	<p>Hovedfunn At 6 months post-randomisation, the proportion of patients with a GOS-E of 4 or lower did not differ between the intervention group and the placebo group in the overall evaluable population in all prespecified subgroups and across different geographical regions. Erythropoietin did not affect the probability of patients having a greater or equal extended GOS-E level relative to a lower level at 6 months.</p> <p>No significant difference in mortality was recorded in patients who were given erythropoietin versus those given placebo.</p> <p>Bifunn No increase in the occurrence of a composite thrombotic outcome, the nature of thrombotic events, upper limb thrombotic events or other adverse events was recorded following the administration of erythropoietin.</p> <p>For the primary outcome and all the secondary outcomes, with the exception of 6-month mortality, no differential effect of erythropoietin was recorded.</p>	<p>Sjekkliste:</p> <ul style="list-style-type: none"> • Er formålet med studien klart formulert? Ja • Ble utvalget fordelt til de ulike gruppene med randomiseringsprosedyre? Ja • Ble alle deltakerne gjort rede for på slutten av studien? Ja • Ble deltakere/studiepersonell blindet mht gruppetilhørighet? Ja • Var gruppene like ved starten? Ja. • Ble gruppene behandlet likt? Ja, foruten intervensjonen • Hva er resultatene? Ingen generaliserbar forskjell mellom gruppene • Kan resultatene overføres til praksis? Ja • Ble alle utfallsmål vurdert? Ja, alle planlagte utfallsmål ble vurdert. • Er fordelene verdt ulemper/kostnader? Ikke aktuelt <p>Hva diskuterer forfatterne om:</p> <p>Styrke God randomisering for å unngå Bias. Sammenlignbar pasientgruppe med andre studier.</p> <p>Svakhet Satt til å detektere over 24% risikoreduksjon, således registreres ikke lavere risikoreduksjon. Pasienter med høy hemoglobin ble ekskludert, kan ikke si noe om denne gruppen.</p> <p>Viser forfatterne til annen litteratur som styrker/svekker resultatene? Nei</p> <p>Har resultatene plausible biologiske forklaringer? Ja.</p>
<p>Konklusjon</p> <p>Erythropoietin did not, at 6 months, reduce the proportion of patients with GOS-E level of 4 or lower, or increase objectively measured proximal deep venous thrombosis, in patients with moderate or severe traumatic brain injury.</p> <p>Land</p> <p>Australia, New Zealand, France, Germany, Finland, Ireland and Saudi-Arabia.</p> <p>År data innsamling</p> <p>Between May 3, 2010 and Nov 1, 2014.</p>			

<p>Referanse: Trimmel, Helmut MD; Kreutziger, Janett MD; Fitzka, Robert MD; Szuts, Stephan MD; Derdak, Christoph MD; Koch, Elisabeth MD; Erwied, Boris MD; Voelckel, Wolfgang G. MD. <i>Use of the GlideScope Ranger Video Laryngoscope for Emergency Intubation in the Prehospital Setting: A Randomized Control Trial.</i> Critical Care Medicine. 44(7):e470-e476, July 2016.</p>		Studiedesign: RCT Grade - kvalitet 1b	
Formål <p>They sought to assess whether the GlideScope Ranger video laryngoscope may be a reliable alternative to direct laryngoscopy in the prehospital setting.</p>		Materiale og metode <p>Rekruttering deltakere (randomisering) Emergency patients more than 18 years old requiring prehospital airway management were enrolled and randomly subjected to GlideScope intubation or direct laryngoscopy. The randomization code was developed by using a computer random number generator. Inclusion criteria: Emergency patients more than 18 years old requiring prehospital airway management Exclusion criteria: Other patients. Outcome: Successful endotracheal airway. Secondary: Time from opening of the mouth until successful glottis passage of the tube and time until first end-tidal CO₂ measurement. Eksponeringsvariabler (validert/ikke validert) GlideScope Ranger video laryngoscope versus conventional direct laryngoscopy. Viktige konfunderende faktorer Not reported Statistiske metoder Mann-Whitney U test, chi-square test and Fisher exact test.</p>	
Konklusjon <p>Prehospital use of the GlideScope was associated with some major problems, thus resulting in a lower intubation success rate when compared with direct laryngoscopy.</p>		Resultater <p>Hovedfunn In this study prehospital endotracheal intubation employing the GlideScope Ranger was less successful when compared with direct laryngoscopy. Two major problems were identified to negatively affect GlideScope intubation success: failure to advance the tube toward the larynx and trachea despite adequate visualization of the airway. Second insufficient delineation of the anatomic structures when blood or fluids were an issue or when bright ambient light impaired the view on the screen. Bifunn Not further discussed.</p>	
Land Austria and Norway År data innsamling April 2011 – September 2012.		Diskusjon/kommentarer/sjekkliste <p>Sjekkliste:</p> <ul style="list-style-type: none"> • Er formålet med studien klart formulert? Ja • Ble utvalget fordelt til de ulike gruppene med randomiseringsprosedyre? Ja • Ble alle deltakerne gjort rede for på slutten av studien? Ja • Ble deltakere/studiepersonell blindet mht gruppetilhørighet? Man trakk konvolutt for å velge metode. • Var gruppene like ved starten? Ja. Samme grupper. • Ble gruppene behandlet likt? Nei, forskjelling intervasjon. Ellers: ja. • Hva er resultatene? Ny metode dårligere enn opprinnelig metode. • Kan resultatene overføres til praksis. Ja. • Ble alle utfallsmål vurdert? Ja • Er fordelene verdt ulemper/kostnader? Det rapporteres ikke fordelor. <p>Hva diskuterer forfatterne om:</p> <p>Styrke Sterkt design. Diskuteres ikke utover dette.</p> <p>Svakhet Funnenne kan gjenspeile ferdigheten til utøverne. Liten trening i bruk av utstyret på forhånd. Viser forfatterne til annen litteratur som styrker/svekker resultatene? Ja, viser til interessant litteratur som tyder på at in-hospital prosedyrer ikke automatisk kan overføres til prehospital settinger.</p> <p>Har resultatene plausible biologiske forklaringer? Ja</p>	

<p>Referanse: Hultling C, Giuliano F, Quirk F, Peña B, Mishra A, Smith MD. Quality of life in patients with spinal cord injury receiving VIAGRA® (sildenafil citrate) for the treatment of erectile dysfunction. Spinal Cord. 2000;38:363.</p>			Studiedesign: RCT
			Grade - kvalitet 1b
Formål	Materiale og metode	Resultater	Diskusjon/kommentarer/sjekkliste
To evaluate the effect of sildenafil citrate (VIAGRA) on the quality of life (QoL) of men with erectile dysfunction (ED) caused by spinal cord injury (SCI).	<p>Rekruttering deltakere (randomisering) The 326 included patients underwent stratified randomization to an intervention group or a control group. The stratification was done by a study assistant.</p> <p>Inclusion criteria: Men at least 18 years of age, a traumatic SCI at least 6 months before screening, a clinical diagnosis of ED solely attributable to injury of the spinal cord, cessation of other therapies for ED, and involvement in a stable relationship with a female partner for at least the past 6 months.</p> <p>Exclusion criteria: Genital anatomical deformities; primary sexual disorder other than ED; major psychiatric or psychological disorder, major depression; DM; history of stroke or myocardial infarction within the last 6 months; cardiovascular disease; regular nitrate therapy; active peptic ulcers; history of retinitis pigmentosa, bleeding disorders, or renal or hepatic abnormalities; and evidence of other medical conditions impairing ability to complete the study.</p> <p>Outcome: Quality of life related to improvement of erectile function in patients with spinal cord injury.</p> <p>Ekspонeringsvariabler (validert/ikke validert) Treatment or not</p> <p>Viktige konfunderende faktorer Not reported</p> <p>Statistiske metoder ANCOVA-test</p>	<p>Hovedfunn Treatment with sildenafil can significantly improve erectile function in men with SCI, including men with no residual erectile function. Overall, the condition-specific QoL measures related to sexual function showed significant improvements after treatment with sildenafil and correlated well with the efficacy in men with ED attributable to SCI. The most dramatic improvement in QoL was seen in the overall satisfaction with sexual life domain of the IIEF, followed by being less bothered by the 'impact of erectile problems' and improvements in 'mental health' and 'depression'.</p>	<p>Sjekkliste:</p> <ul style="list-style-type: none"> • Er formålet med studien klart formulert? Ja • Ble utvalget fordelt til de ulike gruppene med randomiseringsprosedyre? Ja • Ble alle deltakerne gjort rede for på slutten av studien? Ja • Ble deltakere/studiepersonell blindet mht gruppetilhørighet? Ja • Var gruppene like ved starten? Ja • Ble gruppene behandlet likt? Ja, foruten intervasjon • Hva er resultatene? Bedre livskvalitet ved bruk av Sildenafil. • Kan resultatene overføres til praksis. Ja • Ble alle utfallsmål vurdert? Ja, alle relevante. • Er fordelene verdt ulemper/kostnader? Ja ,det er liten kostnad knyttet til medikamentet. <p>Hva diskuterer forfatterne om:</p> <p>Styrke Ikke spesifikt diskutert.</p> <p>Svakhet Kort behandlingstid. Lavt antall inkluderte. Ulike definisjoner av livskvalitet.</p> <p>Viser forfatterne til annen litteratur som styrker/svekker resultatene? Det refereres til relevante sammenlignbare prosjekter.</p> <p>Har resultatene plausible biologiske forklaringer? Ja</p>
Konklusjon	Treatment with sildenafil can significantly improve key QoL parameters in men with ED caused by SCI.		
Land	Study centers in Australia, Belgium, France, Germany, Norway, Sweden and the United Kingdom		
År data innsamling	June 1996 through January 1997		